

# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

***APPLICATION NUMBER:***

**209903Orig1s010**

***Generic or Proper Name:*** Diclofenac Sodium Topical Gel, 1%.

***Sponsor:*** Cipla USA, Inc

***Approval Date:*** July 15, 2024

# CENTER FOR DRUG EVALUATION AND RESEARCH

## 209903Orig1s010

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**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209903Orig1s010**

**APPROVAL LETTER**



ANDA 209903/S-010

**PRIOR APPROVAL SUPPLEMENT  
APPROVAL**

Cipla USA, Inc.  
U.S. Agent for Cipla Limited  
10 Independence Boulevard, Suite 300  
Warren, NJ 07059  
Attention: Michele Crawley  
Director, Regulatory Affairs

Dear Michele Crawley:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on January 25, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Diclofenac Sodium Topical Gel, 1%.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as a "Prior Approval Supplement," provides for:

- Conversion of marketing status from Full Prescription to Over-The-Counter.
- Addition of Bora Pharmaceutical Services Inc. as an alternate drug product manufacturing facility.

We have completed the review of this sANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act for over-the-counter (OTC) use. Accordingly the sANDA is **approved**, effective on the date of this letter. We have determined your Diclofenac Sodium Topical Gel, 1% (OTC), to be bioequivalent to the reference listed drug (RLD), Voltaren Arthritis Pain Topical Gel, 1%, of Haleon US Holdings LLC.

**COMPENDIAL STANDARDS**

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise

official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>.

### **REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

*{See appended electronic signature page}*

For Edward M. Sherwood  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Catherine  
Poole

Digitally signed by Catherine Poole

Date: 7/15/2024 02:12:50PM

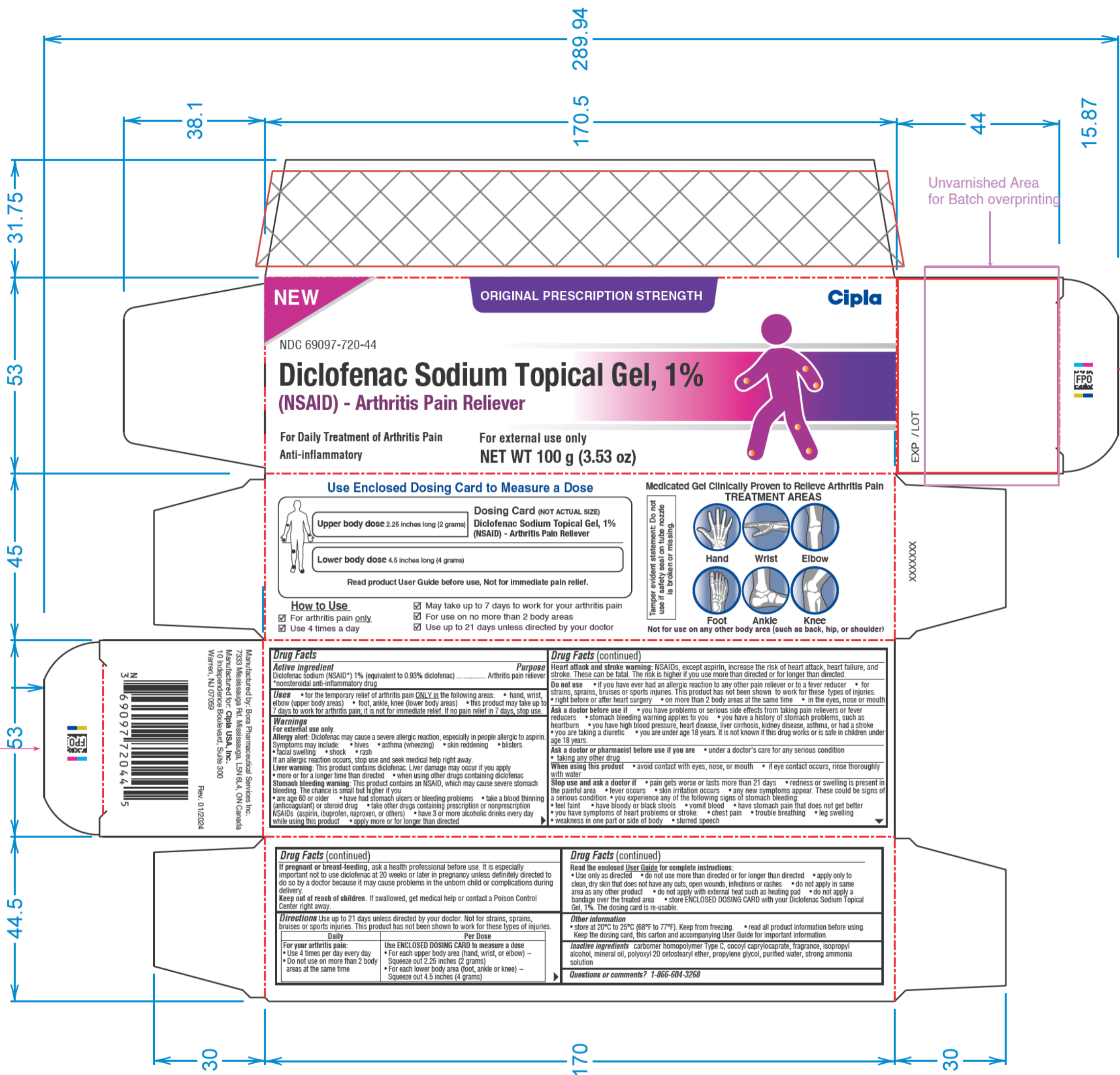
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**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209903Orig1s010**

**LABELING**



**NEW**

**ORIGINAL PRESCRIPTION STRENGTH**

**Cipla**

NDC 69097-720-44

**Diclofenac Sodium Topical Gel, 1%  
(NSAID) - Arthritis Pain Reliever**

For Daily Treatment of Arthritis Pain  
Anti-inflammatory

For external use only  
**NET WT 100 g (3.53 oz)**



**Use Enclosed Dosing Card to Measure a Dose**

**Dosing Card (NOT ACTUAL SIZE)**  
Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever

Upper body dose 2.25 inches long (2 grams)  
Lower body dose 4.5 inches long (4 grams)

Read product User Guide before use, Not for immediate pain relief.

**How to Use**

- For arthritis pain only
- Use 4 times a day
- May take up to 7 days to work for your arthritis pain
- For use on no more than 2 body areas
- Use up to 21 days unless directed by your doctor

Medicated Gel Clinically Proven to Relieve Arthritis Pain

**TREATMENT AREAS**

Hand    Wrist    Elbow  
Foot    Ankle    Knee

Not for use on any other body area (such as back, hip, or shoulder)

Tamper evident seal on tube nozzle is broken or missing.

EXP / LOT

XXXXXX

2D code:  
XXXXXX

2D code:  
XXXXXX

**Drug Facts**

**Active ingredient**  
Diclofenac sodium (NSAID\*) 1% (equivalent to 0.93% diclofenac) ..... Arthritis pain reliever  
\*nonsteroidal anti-inflammatory drug

**Purpose**  
Arthritis pain reliever

**Uses** • for the temporary relief of arthritis pain ONLY in the following areas: • hand, wrist, elbow (upper body areas) • foot, ankle, knee (lower body areas) • this product may take up to 7 days to work for arthritis pain; it is not for immediate relief. If no pain relief in 7 days, stop use.

**Warnings**  
For external use only.  
**Allergy alert:** Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • hives • asthma (wheezing) • skin reddening • blisters • facial swelling • shock • rash  
If an allergic reaction occurs, stop use and seek medical help right away.  
**Liver warning:** This product contains diclofenac. Liver damage may occur if you apply • more or for a longer time than directed • when using other drugs containing diclofenac  
**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while using this product • apply more or for longer than directed

**Drug Facts (continued)**

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use** • if you have ever had an allergic reaction to any other pain reliever or to a fever reducer • for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries. • right before or after heart surgery • on more than 2 body areas at the same time • in the eyes, nose or mouth

**Ask a doctor before use if** • you have problems or serious side effects from taking pain relievers or fever reducers • stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • you are taking a diuretic • you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.

**Ask a doctor or pharmacist before use if you are** • under a doctor's care for any serious condition • taking any other drug

**When using this product** • avoid contact with eyes, nose, or mouth • if eye contact occurs, rinse thoroughly with water

**Stop use and ask a doctor if** • pain gets worse or lasts more than 21 days • redness or swelling is present in the painful area • fever occurs • skin irritation occurs • any new symptoms appear. These could be signs of a serious condition. • you experience any of the following signs of stomach bleeding: • feel faint • have bloody or black stools • vomit blood • have stomach pain that does not get better • you have symptoms of heart problems or stroke: • chest pain • trouble breathing • leg swelling • weakness in one part or side of body • slurred speech

**Drug Facts (continued)**

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.  
**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** Use up to 21 days unless directed by your doctor. Not for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.

Daily	Per Dose
For your arthritis pain: • Use 4 times per day every day • Do not use on more than 2 body areas at the same time	Use ENCLOSED DOSING CARD to measure a dose • For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams) • For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)

**Drug Facts (continued)**

**Read the enclosed User Guide for complete instructions:**  
• Use only as directed • do not use more than directed or for longer than directed • apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes • do not apply in same area as any other product • do not apply with external heat such as heating pad • do not apply a bandage over the treated area • store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel, 1%. The dosing card is re-usable.

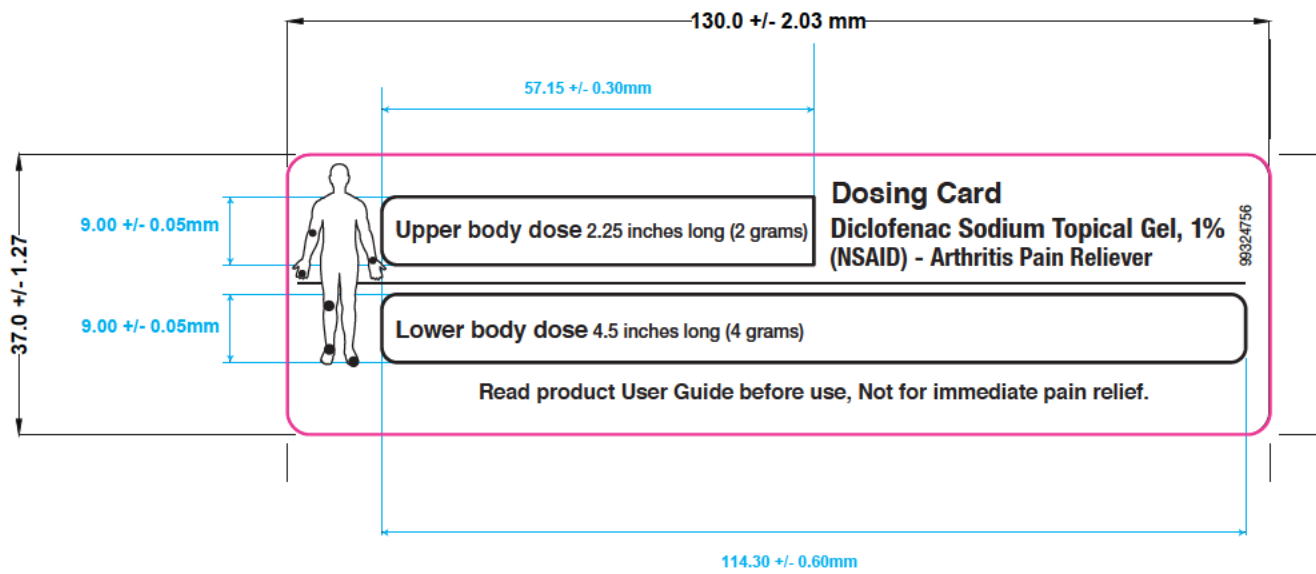
**Other information**  
• store at 20°C to 25°C (68°F to 77°F). Keep from freezing. • read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.

**Inactive ingredients** carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution

**Questions or comments? 1-866-604-3268**



(b) (4)



(b) (4)

20 mm

**To open tube: Unscrew cap and press the spike on the top of the cap onto the seal on the tube.**

**This tube does not contain full product information.**

**Retain outer carton, dosing card, and User Guide for full product uses, directions and warnings.**

**Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.**

**Warnings**

**For external use only**

**Allergy alert:** Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Liver warning:** This product contains diclofenac. Liver damage may occur if you apply

- more or for a longer time than directed
- when using other drugs containing diclofenac

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- apply more or for longer than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**  
• store at 20°C to 25°C (68°F to 77°F). Keep from freezing.

**Questions or comments? 1-866-604-3268**

Manufactured by: Bora Pharmaceutical Services Inc.  
7333 Mississauga Rd. Mississauga, L5N 6L4, ON Canada  
Manufactured for: Cipla USA, Inc.  
10 Independence Boulevard, Suite 300, Warren, NJ 07059

Rev. 01/2024

Lot and Exp.



"Lot and Exp." to be printed on the tube with a laser, during commercial packing

NDC 69097-720-44

# Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever

NET WT 100 g (3.53 oz)



(b) (4)

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## **Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever**

### **User Guide**

#### **How to use Diclofenac Sodium Topical Gel (NSAID), with answers to frequently asked questions**

#### **Quick Start**

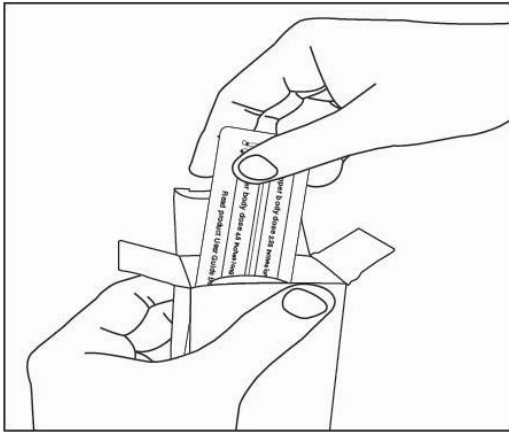
#### **How to get started right away with Diclofenac Sodium Topical Gel (NSAID)**

#### **Understanding Diclofenac Sodium Topical Gel (NSAID)**

Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever is an arthritis pain relief medication that you apply to your skin. It is intended to be used 4 times a day every day for up to 21 days.

#### **Before You Use Diclofenac Sodium Topical Gel (NSAID)**

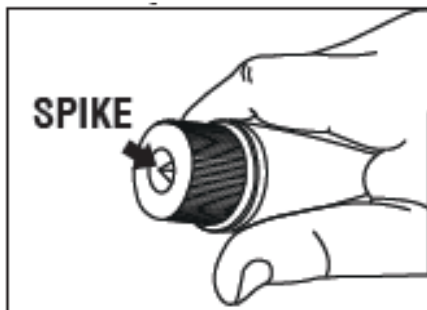
Read the Drug Facts Label, which appears on the carton.



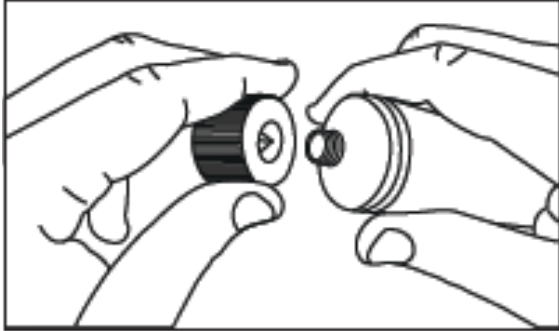
Remove the dosing card from the inside of the carton. You should always use the dosing card to measure out the correct dose of Diclofenac Sodium Topical Gel (NSAID).

#### **The first time you use a tube of Diclofenac Sodium Topical Gel (NSAID):**

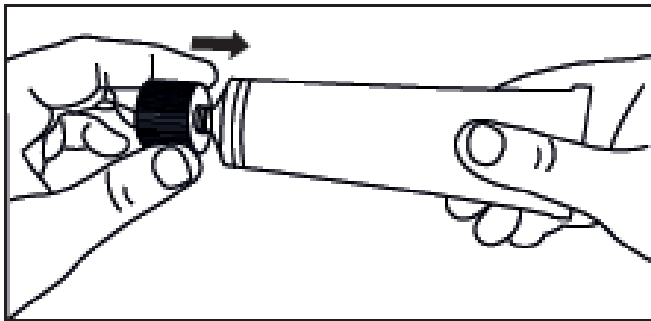
**You will have the cap as shown below.**



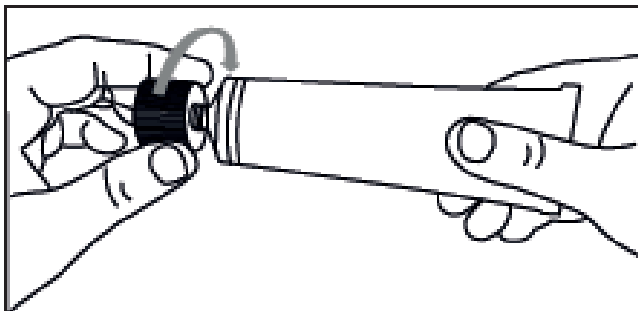
1. Take the cap off the tube.



2. Open the safety seal by firmly pressing the spike on the top of the cap onto the seal on the tube. Do not open the safety seal with scissors or other sharp objects.



3. After use, put the cap back on the end of the tube.



### **Using Diclofenac Sodium Topical Gel (NSAID)**

#### **How often to use Diclofenac Sodium Topical Gel (NSAID)**

Use 4 times a day for best results.

For example:



Start of the day



Middle of the day



Late afternoon

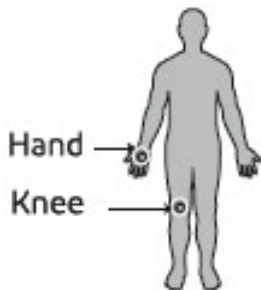


End of the day

### Where to apply Diclofenac Sodium Topical Gel (NSAID)

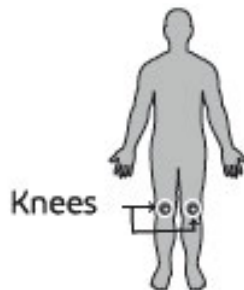
Diclofenac Sodium Topical Gel (NSAID) can be used on up to 2 body areas from the following list: a hand, a wrist, an elbow, a foot, an ankle, a knee. Do not use on more than 2 body areas at once.

Some examples include:



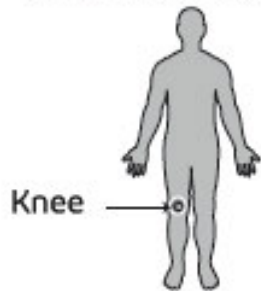
Hand  
Knee

✓ **Correct: 2 areas**



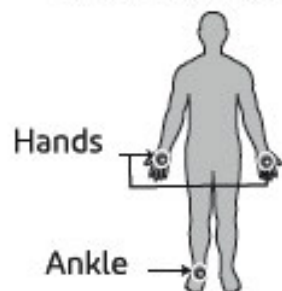
Knees

✓ **Correct: 2 areas**



Knee

✓ **Correct: 1 area**

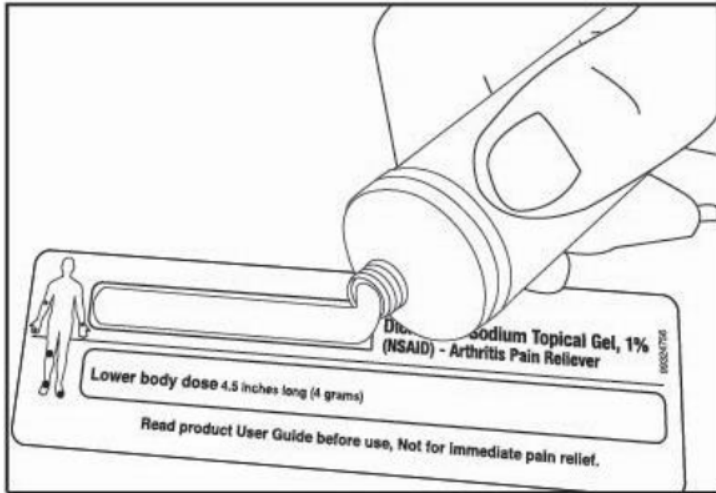


Hands

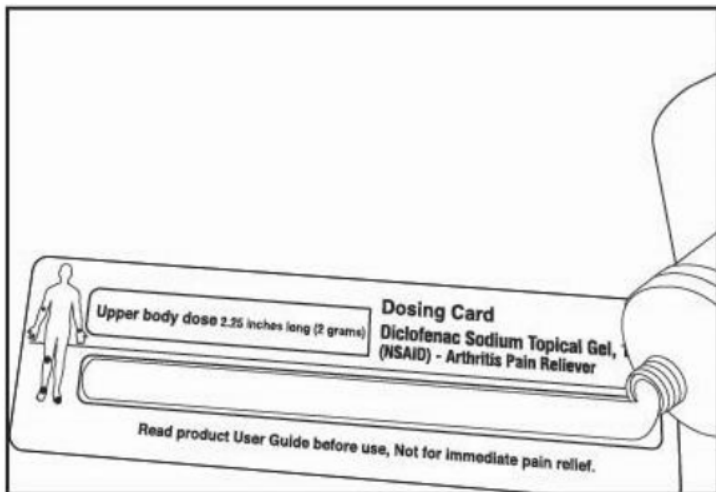
Ankle

✗ **Incorrect: 3 areas**

## Measuring the correct amount using the dosing card



**For each upper body area** (a hand, a wrist, or an elbow): Squeeze gel from the tube equal to the length shown on the upper body section of the dosing card (2.25 inches).



**For each lower body area** (a foot, an ankle, or a knee): Squeeze gel from the tube equal to the length shown on the lower body section of the dosing card (4.5 inches).

**Lost your dosing card? Don't worry!**  
**Call 1-866-604-3268 to get a free replacement.**

## Applying Diclofenac Sodium Topical Gel (NSAID)

Gently rub Diclofenac Sodium Topical Gel (NSAID) into the skin using your hand. Apply 4 times a day for best results. Do not use on more than 2 body areas at once.

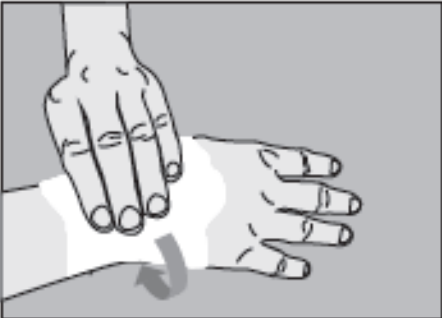
Apply only to clean, dry skin that doesn't have any cuts, open wounds, infections or rashes. Do not apply in the same area as any other medicines or products that are applied to the skin.

**Upper body areas**



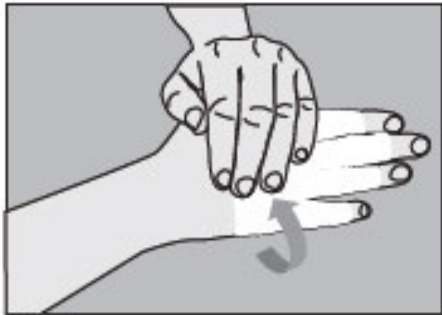
**Elbow**

Including sides, inner, and outer



**Wrist**

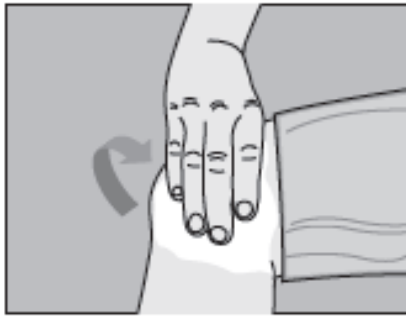
Including sides, top, and bottom



**Hand**

Including top, palm, and fingers

**Lower body areas**



**Knee**

Including sides, kneecap, and back



**Ankle**

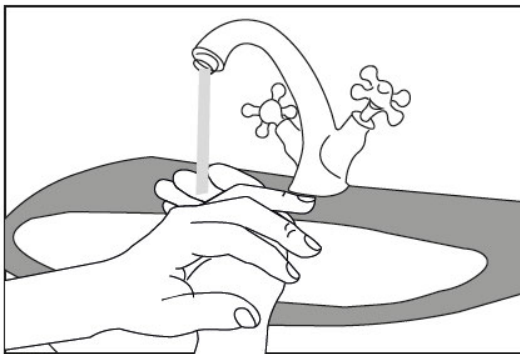
Including sides, front, and back



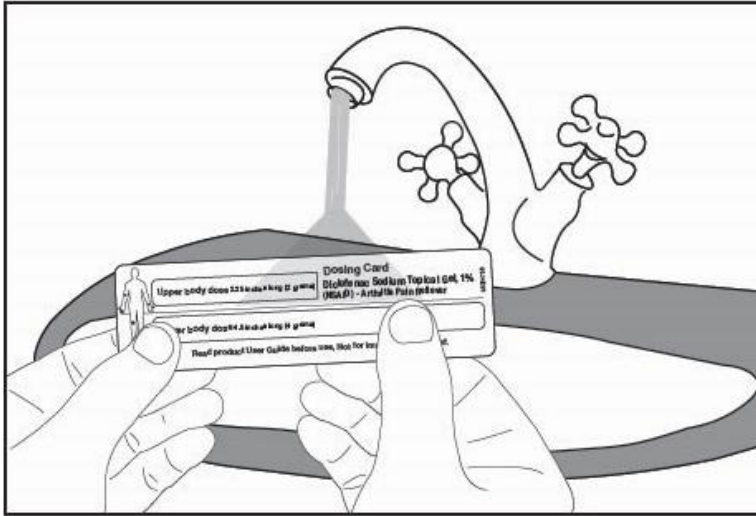
**Foot**

Including sole, top of foot, and toes

**After You Use Diclofenac Sodium Topical Gel (NSAID)**



**Wash your hands** after applying Diclofenac Sodium Topical Gel (NSAID). If the treated area is the hands wait up to 1 hour to wash the hands.



**Wash the dosing card** with water. Store dosing card with your Diclofenac Sodium Topical Gel (NSAID) and keep out of reach of children.



**Wait ten minutes** before covering the treated areas with clothes or gloves.

**Avoid:**

- showering or bathing for at least 1 hour after use
- exposing the treated area to sunlight or artificial light (such as in tanning booths)
- use in same area as other products applied to the skin
- applying a bandage over the treated area
- eye, nose, or mouth contact. If eye contact occurs, rinse thoroughly with water

**Facts you need to know**

**Important information about Diclofenac Sodium Topical Gel (NSAID)**

**Do not use Diclofenac Sodium Topical Gel (NSAID)...**

- if you have ever had an allergic reaction to any other pain reliever or to a fever reducer
- for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries
- right before or after heart surgery

- on more than 2 body areas at the same time
- in the eyes, nose or mouth

**Ask a doctor before use if...**

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.

**Ask a doctor or pharmacist before use if...**

- you are under a doctor's care for any serious condition
- you are taking any other drug
- you are pregnant or breast-feeding

It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Warnings to consider before use...**

**Allergy alert**

Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- |                     |                   |
|---------------------|-------------------|
| • hives             | • blisters        |
| • asthma (wheezing) | • facial swelling |
| • skin reddening    | • shock           |
| • rash              |                   |

If an allergic reaction occurs, stop use and seek medical help right away.

**Liver warning**

This product contains diclofenac. Liver damage may occur if you apply

- more or for a longer time than directed
- when using other drugs containing diclofenac

**Stomach bleeding warning**

This product contains an NSAID, which may cause stomach bleeding. The chance is small but higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- apply more or for longer than directed

### **Heart attack and stroke warning**

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. This can be fatal. The risk is higher if you use more than directed or for longer than directed.

### **Follow these important guidelines when using Diclofenac Sodium Topical Gel (NSAID)...**

- use only as directed
- apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes
- do not apply in same area as any other product used on the skin
- do not apply with external heat such as heating pad
- do not apply a bandage over the treated area
- do not get gel in eyes, nose or mouth
- store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel (NSAID). The dosing card is re-usable.

### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

### **Stop using Diclofenac Sodium Topical Gel (NSAID) and ask a doctor if...**

- pain gets worse or lasts more than 21 days
- redness or swelling is present in the painful area
- fever occurs
- skin irritation occurs
- any new symptoms appear. These could be signs of a serious condition.
- you experience any of the following signs of stomach bleeding:

- feel faint
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better

- you have symptoms of heart problems or stroke:

- chest pain
- trouble breathing
- leg swelling
- weakness in one part or side of body
- slurred speech

### **Question and Answers**

#### **Answers to questions you may ask about Diclofenac Sodium Topical Gel (NSAID)**

**Can I use Diclofenac Sodium Topical Gel (NSAID) for the immediate relief of pain like that associated with sprains, strains, bruises or sports injuries?**

**No.**

Do not use for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries. It's intended only for the temporary relief of arthritis pain.

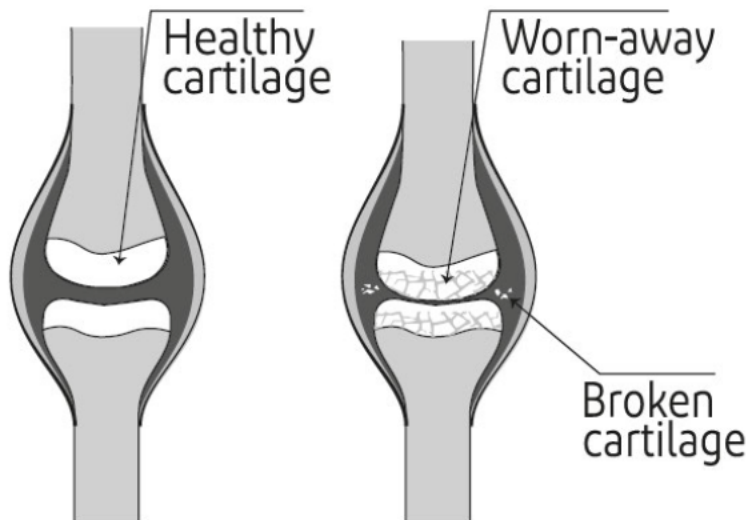
**How quickly will Diclofenac Sodium Topical Gel (NSAID) work for arthritis pain?**

Diclofenac Sodium Topical Gel (NSAID) may take up to 7 days to work for your arthritis pain; it is not for immediate relief. With 4 times-a-day use, you may start to feel relief within a few days. You should feel significant pain relief within 7 days of continuous use. If no pain relief in 7 days, stop use.

**What is Diclofenac Sodium Topical Gel (NSAID) used for?**

Diclofenac Sodium Topical Gel (NSAID) can be used for the temporary relief of arthritis pain in the hands, wrists, elbows, feet, ankles, and knees. Osteoarthritis (OA) is the most common form of arthritis. It mainly affects a type of tissue called cartilage, which cushions the joints and prevents the bones from rubbing against each other.

With OA, cartilage begins to break down and wear away, resulting in joint pain and stiffness. OA occurs more frequently as you get older. Pain develops slowly and can gradually worsen over time.



**How does Diclofenac Sodium Topical Gel (NSAID) work?**

Diclofenac sodium, the medicine in Diclofenac Sodium Topical Gel (NSAID), is a nonsteroidal anti-inflammatory drug (NSAID). NSAIDs are used to treat pain from medical conditions such as arthritis. Diclofenac Sodium Topical Gel (NSAID) works similarly to oral NSAIDs like ibuprofen or naproxen by temporarily blocking the production of pain signaling chemicals called prostaglandins. However, when taking a pill, the medication is distributed to the site of pain through the bloodstream. Compared to oral diclofenac, only 6% of the medicine in Diclofenac Sodium Topical Gel (NSAID) is absorbed in the bloodstream. It works by penetrating through your skin at the application site to deliver arthritis pain relief.

**How does over-the-counter Diclofenac Sodium Topical Gel (NSAID) differ from prescription Diclofenac Sodium Topical Gel (NSAID)?**

Over-the-counter Diclofenac Sodium Topical Gel (NSAID) is the same strength and formula as original full prescription strength Diclofenac Sodium Topical Gel (NSAID) but is available without a prescription.

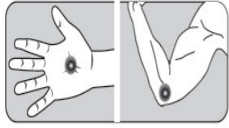
Apply Diclofenac Sodium Topical Gel (NSAID) 4 times a day to ensure you get the full effect of the medicine.

**Can I apply Diclofenac Sodium Topical Gel (NSAID) to upper and lower body areas at the same time?**

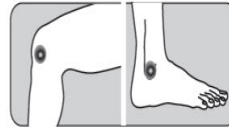
**Yes.**

You can use Diclofenac Sodium Topical Gel (NSAID) on up to 2 body areas at the same time. The areas can include the foot, ankle, knee, hand, wrist, and elbow.

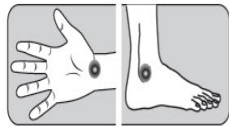
Some correct examples include:



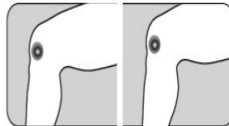
**Upper body**  
Hand and elbow



**Lower body**  
Knee and ankle



**Upper/Lower body**  
Wrist and ankle



**Lower body**  
(L)Knee and (R)knee

*Do not use Diclofenac Sodium Topical Gel (NSAID) on more than 2 body areas at once.*

**Can I apply Diclofenac Sodium Topical Gel (NSAID) without measuring it out on the dosing card first?**

**No.**

Use the dosing card to make sure you are getting the correct amount of medicine.

**Can I use Diclofenac Sodium Topical Gel (NSAID) on my spine, hips, or shoulders?**

**No.**

The use of Diclofenac Sodium Topical Gel (NSAID) on the spine, hips, and shoulders has not been studied.

**Can I take any other pain medications with Diclofenac Sodium Topical Gel (NSAID)?**

Ask your doctor or pharmacist before using Diclofenac Sodium Topical Gel (NSAID) if you are taking any other pain reliever or are planning on taking any other pain reliever, especially prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others).

**Can I take any other pain medications during the first 7 days I use Diclofenac Sodium Topical Gel (NSAID)?**

Taking other pain medications is generally not recommended. Speak with your doctor or pharmacist before taking other pain medications when using Diclofenac Sodium Topical Gel (NSAID).

**How long can I use Diclofenac Sodium Topical Gel (NSAID)?**

Use Diclofenac Sodium Topical Gel (NSAID) 4 times a day every day for up to 21 days for treatment of arthritis pain or as directed by your doctor.

Diclofenac Sodium Topical Gel (NSAID) should be part of an overall program for managing your arthritis pain. The program should also include activities such as appropriate movement or exercise, specific lifestyle changes, and weight maintenance. Regular visits and discussions with your doctor can help incorporate Diclofenac Sodium Topical Gel (NSAID) into a complete program to help manage your arthritis pain.

**What do I do if I get Diclofenac Sodium Topical Gel (NSAID) in my eyes?**

If eye contact occurs, rinse thoroughly with water and consult a doctor if irritation lasts more than an hour.

**How do I clean the dosing card?**

Wash the dosing card with water, and store dosing card and tube out of reach of children.

**What if I miss a dose of Diclofenac Sodium Topical Gel (NSAID)?**

If you forget to apply Diclofenac Sodium Topical Gel (NSAID), don't double your dose. Just apply the next dose as scheduled.

**How should I store Diclofenac Sodium Topical Gel (NSAID)?**

- Store at 20°C to 25°C (68°F to 77°F).
- Do not freeze Diclofenac Sodium Topical Gel (NSAID).
- Store the dosing card with your Diclofenac Sodium Topical Gel (NSAID).
- Keep out of reach of children.

Helpful Tip: If you forget to apply Diclofenac Sodium Topical Gel (NSAID), don't double your dose. Just apply the next dose as scheduled.

**Additional Questions?**

Call the Diclofenac Sodium Topical Gel (NSAID) consumer hotline at 1-866-604-3268.

**Manufactured by:**

Bora Pharmaceutical Services Inc.  
7333 Mississauga Rd, Mississauga,  
L5N 6L4, Canada

**Manufactured for: Cipla USA, Inc.**

10 Independence Boulevard, Suite 300  
Warren, NJ 07059

Revised: 1/2024

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209903Orig1s010**

**LABELING REVIEW(s)**

**PRIOR APPROVAL SUPPLEMENT LABELING REVIEW**

Division of Labeling Review  
 Office of Regulatory Operations  
 Office of Generic Drugs (OGD)  
 Center for Drug Evaluation and Research (CDER)

<b>Date of This Review</b>	March 1, 2024
<b>ANDA Number(s) and Supplement Number(s)</b>	209903/S-010
<b>Review Number</b>	1
<b>Applicant Name</b>	Cipla Limited
<b>Established Name &amp; Strength(s)</b> [Add "(OTC)" after strength if applicable]	Diclofenac Sodium Topical Gel, 1% (OTC)
<b>Proposed Proprietary Name</b>	NA
<b>Submission Received Date</b>	January 25, 2024
<b>Previous Received Date(s) of Proposed Supplement</b>	NA
<b>Primary Labeling Reviewer</b>	Andrew Choi
<b>Secondary Labeling Reviewer</b>	Burhan Nour
<b>Review Conclusion</b> <input checked="" type="checkbox"/> Acceptable - No Comments <input type="checkbox"/> Acceptable - Include Post Approval Comments <input type="checkbox"/> Minor Deficiency* - Refer to Labeling Deficiencies and Comments for Letter to Applicant <input type="checkbox"/> Major Deficiency** - Refer to Labeling Deficiencies and Comments for Letter to Applicant	
On Policy Alert List <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Acceptable For Filing <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Combined Insert/Outsert <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

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## 1 LABELING COMMENTS

### For combined supplement(s):

The Division of Labeling Review has no comments. Labeling is acceptable.

## 2 INSTRUCTIONS FOR ASSESSMENT

### General Comments:

Select the "no deficiency" or "deficiency" radio button as appropriate for each row. If a "Deficiency Comments" appears, ensure it is appropriate for your situation, edit, or enter "Reviewer Comments" if necessary.

If there is no issue/concern, or if the question is not applicable. No "Deficiency Comments" will appear but reviewers can still enter "Reviewer Comments" if desired.

<input type="checkbox"/>	<input checked="" type="checkbox"/>	There is information in the Orange Book that the applicant needs to address.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Information in the Orange Book has expired and the applicant needs to revise labeling.

### Reviewer Comments:

Enter free text in this section as necessary.

### Deficiency Comments:

- Standardized comments/deficiencies are available for certain questions. For a complete list of standardized comments, reference the [DLR Standardized Comments](#) SharePoint.
- Reviewers can modify standardized comments/deficiencies for their situation.
- Deficiencies will have a review number, deficiency number, and roman numeral in the user interface. For first original reviews the review number and iteration numeral will align; however, older reviews may have review numbers and iteration numerals that differ due to some reviews being completed under past practices.

## 3 OVERALL ASSESSMENT OF MATERIALS REVIEWED

Table 1: Review Summary of Container Label and Carton Labeling				
	Final or Draft or NA	Packaging Sizes	Submission Received Date	Recommendation
Container	N/A	N/A		
Blister	N/A	N/A		
Carton	Draft	1 tube (100 g)	1/25/24	Satisfactory
Tube	Draft	100 g	1/25/24	Satisfactory
Dosing Card	Draft	1 card	1/25/24	Satisfactory

Table 2: Review Summary of Prescribing Information and Patient Labeling				
	Final or Draft or NA	Revision Date and/or Code	Submission Received Date	Recommendation
Prescribing Information	N/A	N/A		
Medication Guide	N/A	N/A		
Patient Information	N/A	N/A		
Instructions for Use	N/A	N/A		
SPL Data Elements				

**Table 2: Review Summary of Prescribing Information and Patient Labeling**

	Final or Draft or NA	Revision Date and/or Code	Submission Received Date	Recommendation
User Guide	Draft	01/24	1/25/24	Satisfactory

**4 LABELING REVIEW INFORMATION**

**4.1 REGULATORY INFORMATION**

Type of Supplement(s): PAS - Other	
<b>Yes</b>	<b>No</b>
<input type="checkbox"/>	<input checked="" type="checkbox"/> Are there any applicable issues in <a href="#">DLR's SharePoint Drug Facts</a> ?
<input type="checkbox"/>	<input checked="" type="checkbox"/> Is the drug product listed in the Policy Alert Tracker on <a href="#">OGD's SharePoint</a> ?
<input type="checkbox"/>	<input checked="" type="checkbox"/> Is the drug product listed on the <a href="#">Susceptibility Test Interpretive Criteria</a> web page?
<b>Reason for Submission:</b>	
<p>Cipla intends to obtain approval for the following two changes:</p> <ol style="list-style-type: none"> <li>1. Change the marketing category from Full prescription (Rx) to over-the-counter (OTC), to be in line with RLD, Voltaren arthritis pain, NDA N022122</li> <li>2. Addition of an Alternate Manufacturing Site, Bora Pharmaceutical Services Inc. (BPSI) FEI # 3002807086, for drug product manufacture.</li> </ol>	
Is this supplement combined with another discipline?	Yes
Is this product an OTC product?	Yes
Is this ANDA the RLD?	No

**4.2 MODEL PRESCRIBING INFORMATION**

**Table 3: Review Model Labeling for Prescribing Information/Patient Labeling (Check the box used as the Model Labeling)**

<input checked="" type="checkbox"/> <b>MOST RECENTLY APPROVED <u>NDA</u> MODEL LABELING</b> <i>(If NDA is listed in the discontinued section of the Orange Book, indicate whether the application has been withdrawn and if so, enter the most recently approved ANDA labeling information as applicable.)</i> <b>NDA#/Supplement# (S-000 if original):</b> NDA022122 / S-025 <b>Supplement Approval Date:</b> 11/29/2023 <b>Proprietary Name:</b> Voltaren Arthritis Pain Gel <b>Established Name:</b> diclofenac sodium gel <b>Description of Supplement:</b>  <p>This "Prior Approval" sNDA provides for changes to the layout of approved content on panels and an update to the dosing card graphics to reflect the smaller dosing card approved for the 20 g pack in Supplement 014.</p> <b>Link:</b> <a href="https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af8070cbca">https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af8070cbca</a>
<input type="checkbox"/> <b>MOST RECENTLY APPROVED <u>ANDA</u> MODEL LABELING</b>

Table 3: Review Model Labeling for Prescribing Information/Patient Labeling (Check the box used as the Model Labeling)
<input type="checkbox"/> OTHER/TEMPLATE (e.g., Pending Supplements, BPCA, PREA, Carve-out):
Reviewer Comments:
Deficiency Comments:

**4.3 PATENTS AND EXCLUSIVITIES**

The [Orange Book](#) was searched on 03/01/2024

Table 4 provides Orange Book patents for the Model Labeling (NDA022122) and ANDA patent certifications. (For applications that have no patents, N/A is entered in the patent number column.)

Table 4: Impact of Model Labeling Patents on ANDA Labeling							
Strengths	Patent Number	Patent Expiration	Patent Use Code	Patent Use Code Definition	Patent Certification	Date of Patent Cert Submission	Labeling Impact
	N/A						

Table 5 provides Orange Book exclusivities for the Model Labeling and ANDA exclusivity statements.

Table 5: Impact of Model Labeling Exclusivities on ANDA Labels and Labeling						
Strengths	Exclusivity Code	Exclusivity Expiration	Exclusivity Code Definition	Exclusivity Statement	Date of Exclusivity Submission	Labeling Impact
	N/A					

**Reviewer Assessment:**

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	There is information in the Orange Book that the applicant needs to address.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Information in the Orange Book has expired and the applicant needs to revise labeling.
Reviewer Comments:		
Deficiency Comments:		

**4.4 UNITED STATES PHARMACOPEIA (USP)**

The [USP](#) was searched on 03/01/2024

Table 6: USP				
	YES or NO	Date	Monograph Title (N/A if no monograph)	Packaging and Storage/Labeling Statements (N/A if no monograph)
Currently Official	No		N/A	N/A
Not Yet Official	No		N/A	N/A

**Reviewer Assessment:**

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Established name is acceptable with regard to the USP monograph or the RLD's nonproprietary name.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	RLD's non-proprietary name is different from USP established name.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	USP descriptor is correctly used in the appropriate sections of the prescribing information.
USP RECOMMENDATIONS and/or DIFFERENCES IN TEST METHODS (QUALITY):		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	DISSOLUTION: The applicant's dissolution statement is appropriate.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	ORGANIC IMPURITIES: Drug product meets USP acceptance criteria for organic impurities.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	ASSAY: Drug product meets USP acceptance criteria for assay.
Reviewer Comments:		
Deficiency Comments:		

**4.5 MODEL CONTAINER LABELS**

Model container/carton/blister labels (Source: NDA 022122, S-025, approved 11/29/23 )

The image displays two examples of drug labels for Voltaren. The top label is a 'Drug Facts' label, which includes sections for 'Do not use', 'Ask a doctor before use if', and 'Other information'. The bottom label is a 'Directions' label, which includes 'Daily' and 'Per Dose' instructions, 'Other information', and 'Inactive ingredients'. Below the labels is a partial view of the Voltaren product packaging, showing the brand name 'Voltaren' and 'ARTHRITIS PAIN'.



#### 4.6 HISTORY OF ANDA

We evaluated previously approved supplements (Table 7) to determine if actions are needed for the current review.

Table 7: History of ANDA		
Last approved addressed the following:		
Original or Supplement	Approval Date	What post approval changes requested and were the changes addressed?
Orig	08/03/2018	<ol style="list-style-type: none"> <li>Dosing Card Revise patient statement to be consistent with the model labeling as such: Please use Instructions for Use.</li> <li>Container and Carton Labeling Revise the dosing card statement to appear in title case to improve readability.</li> <li>Instructions for Use Review and revise and the spacing of the first bullet point under the subheading. "Some examples of diclofenac sodium topical gel application include:"</li> </ol> <p>Comments have been revised with the updated OTC labeling.</p>

Table 7: History of ANDA

(b) (4)

Are there any Pending Labeling Supplements for this ANDA that impact labeling? NO

5 ASSESSMENT OF CURRENT SUPPLEMENT'S LABELING

5.1 QUALITY INFORMATION (DESCRIPTION, HOW SUPPLIED, AND MANUFACTURER)

5.1.1 DESCRIPTION/INACTIVE INGREDIENTS

Table 8: Comparison of DESCRIPTION Section or Inactive Ingredients Section (OTC)

Model Labeling	<b><i>inactive ingredients</i></b> carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution
Approved ANDA Labeling	The inactive ingredients in diclofenac sodium topical gel include: carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, and strong ammonia solution.
Proposed ANDA Labeling	<b><i>inactive ingredients</i></b> carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution

**Reviewer Assessment:**

Deficiency	No Deficiency	
------------	---------------	--

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	The <b>inactive ingredients</b> in the labeling are consistent with the Composition Statement in Module 3.2.P.1 of the submission. Please enter Reviewer/Deficiency Comments if you select Deficiency.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	For products required to be <b>qualitatively and quantitatively</b> the same in regards to active and inactive ingredients (Q1/Q2), are the ANDA ingredients consistent with the Model Labeling? Please enter Reviewer/Deficiency Comments if you select Deficiency.
Appropriate <b>warning/precaution</b> statements for inactive ingredients are present (21 CFR 201) <b>Check only if applicable:</b>		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> Sulfite ( <a href="#">21 CFR 201.22</a> ) <input type="checkbox"/> Yellow #5 (Tartrazine) ( <a href="#">21 CFR 201.20</a> ) <input type="checkbox"/> Phenylalanine/aspartame ( <a href="#">21 CFR 201.21</a> ) <input type="checkbox"/> Latex ( <a href="#">21 CFR 801.437</a> ). Please enter Reviewer/Deficiency Comments if you select Deficiency.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<b>Sterile product statement</b> [ <a href="#">21 CFR 201.57(c)(12)(i)(D)</a> ].
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<b>Alcohol</b> is properly listed [ <a href="#">21 CFR 201.10(d)(2)</a> ].
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<b>Gluten</b> statement is appropriately stated.

**Reviewer Comments:**

Note: The applicant's proposal for the additional site, Bora Pharmaceutical Services.

**1.14.1.1 Draft Carton and Container Labels (OTC Labels)**

**Reviewer Note:** In this supplement for full Rx to OTC switch, Cipla proposes to commercialize Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever, manufactured at DPT Laboratories Ltd., **and at the proposed additional manufacturing site Bora Pharmaceutical Services Inc. (once approved) under OTC category.** Accordingly, draft carton and tube labels for both sites are provided in this section. The text matter of carton and tube labels applicable for both sites are same except for the change in manufacturing site details under "Manufactured by" for respective site.

**3.2.P.1.2 Composition**

The qualitative and quantitative composition of the drug product stating the name, quality standard (grade), pharmaceutical function, and concentration of each ingredient used in the manufacturing of Diclofenac Sodium Topical Gel 1% w/w are provided in the below table 1. **Cipla submitted a controlled correspondence (# 942218) to the Agency for the determination of Q1 and Q2 (qualitatively and quantitatively) sameness of Cipla's formulation to that of RLD (Voltaren®). Agency concluded that Cipla's proposed formulation is Q1 and Q2 to the RLD.** The response for the controlled correspondence # 942218 provided by the Agency is included in module 1.2.

Table 1: Qualitative and quantitative composition of Diclofenac sodium topical gel 1% w/w (Cipla Ltd Goa (b) (4) proposed Additional site Bora)

Name of Ingredients	Standard Quantity			Function
	mg/gm	%w/w (b) (4)	%w/w (Bora)	
<sup>1</sup> Diclofenac Sodium USP	(b) (4)	(b) (4)	(b) (4)	Active
Propylene Glycol USP	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Isopropyl Alcohol USP	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Carbomer Homopolymer (b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
<sup>2</sup> Strong ammonia solution NF	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Mineral oil USP (b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Cocoyl caprylocaprate (b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Polyoxyl 20 cetostearyl ether NF (b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
<b>Total Weight</b>	1000.00	100.00	100.00	---

The applicants listed inactive ingredients are consistent with the listed composition in Module 3, Drug Product Review is still pending and we defer to this assessment.

**Deficiency Comments:**

**5.1.2 HOW SUPPLIED/STORAGE AND HANDLING**

Table 9: Comparison of HOW SUPPLIED Section or Packaging Sizes for OTC Products

	100 g tube
<b>Model Labeling</b>	<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F). Keep from freezing.</li> <li>read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.</li> </ul>
<b>Approved ANDA Labeling</b>	<p><b>16 HOW SUPPLIED/STORAGE AND HANDLING</b></p> <p>Diclofenac sodium topical gel, 1% is a white opaque gel available in aluminium tubes with polypropylene cap containing 100 grams of the topical gel. Each tube contains diclofenac sodium, USP in a gel base (10 mg of diclofenac sodium, USP per gram of gel or 1%). 100 grams tube ..... NDC 69097-524-44</p> <p><u>Storage</u> Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Keep from freezing. Store the dosing card with your diclofenac sodium topical gel.</p>
<b>Proposed ANDA Labeling</b>	<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20°C to 25°C (68°F to 77°F). Keep from freezing.</li> <li>read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.</li> </ul>

**Reviewer Assessment:**

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Physical description (e.g. scoring, color, imprint, capsule size, nozzle tip, cap color) of the finished product in the HOW SUPPLIED section are appropriately displayed
<input type="checkbox"/>	<input checked="" type="checkbox"/>	All submitted labels and labeling are consistent with the HOW SUPPLIED section.

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Drug product is the <b>same color</b> as the RLD's drug product as required (e.g. warfarin, levothyroxine, enoxaparin).
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<b>Storage or dispensing statement</b> is acceptable compared to the RLD/USP monograph.
<b>Reviewer Comments:</b>		
<p>3.2. P.1.5 Container Closure System  Diclofenac sodium topical gel 1% w/w is packaged in (b) (4) tube with polypropylene cap. Dosing card made up of Polypropylene material is provided separately in the carton. Full details and specification of packaging components are given in Module 3.2.P.7 (Container closure system) of this application.</p> <p>Acceptable revisions to follow RLD and for the conversion from Rx to OTC labeling.</p>		
<b>Deficiency Comments:</b>		

**5.1.3 MANUFACTURER, DISTRIBUTOR, AND/OR PACKER**

Table 10: Manufacturer/Distributor/Packer Statements		
<b>Approved ANDA Labeling</b>	Manufactured by: Cipla Ltd., Verna Goa, India  Manufactured for: Cipla USA, Inc. 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL 33323  Revised: 3/2018	
<b>Proposed ANDA Labeling</b>	Manufactured by: Bora Pharmaceutical Services Inc. 7333 Mississauga Rd. Mississauga, L5N 6L4, ON Canada Manufactured for: <b>Cipla USA, Inc.</b> 10 Independence Boulevard, Suite 300 Warren, NJ 07059  Rev. 01/2024	
<b>Assessment</b>	Per 3.2.P.3.1.2., Manufacturers	

Table 10: Manufacturer/Distributor/Packer Statements

<b>3.2.P.3.1.2 Cipla's U</b>	
<b>US Agent Address</b>	
<p><b>Cipla USA, Inc.</b>          10 Independence          Boulevard,          Suite 300,          Warren, New Jersey,          07059, United States</p>	
<p><b>Bora          Pharmaceutical          Services Inc.</b></p>	<p>7333 Mississauga          Rd, Mississauga,          Ontario, L5N          6L4, Canada          (CAN)</p>

Table 10: Manufacturer/Distributor/Packer Statements

Manufactured by	Manufactured for	Distributed by	Distributed for
-----------------	------------------	----------------	-----------------

EDR Link:

**Reviewer Assessment:**

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Manufacturer/Distributor/Packager statement is acceptable <a href="#">[21 CFR 201.1(h)(5) or (6)]</a> or <a href="#">21 CFR 201.1(i)]</a>

**Reviewer Comments:**

From a labeling perspective the "Manufactured for:" and "Manufactured by:" statements are consistent with the Quality submission. We defer to the pending Quality assessment.

**Deficiency Comments:**

5.2 CONTAINER AND CARTON LABELS

*Reviewer Assessment:*

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Changes to the package size(s) supported by the container/closure information in Module 3.2.P.7 of the submission?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<a href="#">Tamper evident (controlled substances)</a> requirements are met.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Use of child-resistant closure (CRC) or non-CRC is appropriate. Describe container closure, cite source and any issues in "Reviewer Comments" below.
OVERALL ASSESSMENT:		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Requirements met for the required label statements ( <a href="#">21 CFR 201.15</a> and <a href="#">21 CFR 201.100</a> ).

Reviewer Comments:

(b) (4)

Deficiency Comments:

5.2.1 OPHTHALMIC PRODUCTS

*Reviewer Assessment:*

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Ophthalmic product cap colors match <a href="#">the American Academy of Ophthalmology (AAO) packaging color-coding</a> scheme.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Name of all <b>inactive ingredients</b> are listed appropriately.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<a href="#">Tamper evident (ophthalmic products)</a> requirements are met.

Reviewer Comments:

Deficiency Comments:

### 5.2.2 INJECTABLE PRODUCTS

**Reviewer Assessment:**

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	There is text on the cap/ferrule over seal of this injectable product. If "Yes", does the text comply with the recommendations in USP General Chapter <7> Labeling.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	The cap color is (). <i>NOTE: Black closure system is prohibited, except for Potassium Chloride for Injection Concentrate.</i>

Reviewer Comments:

Deficiency Comments:

### 5.3 PRESCRIBING INFORMATION, PATIENT LABELING, & DRUG FACTS LABELING (OTC)

**Reviewer Assessment:**

Yes	No	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Shared Prescribing Information: If yes please list ANDA numbers.
<input type="checkbox"/>	<input type="checkbox"/>	Dosage form/strength carve out (RLD combined labeling): justification for retaining information for safety/efficacy.

Deficiency	No Deficiency	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Labeling contained in the submission is the same as the review model labeling (not including allowable differences under <a href="#">21 CFR 314.94(a)(8)</a> .

Reviewer Comments:

(b) (4)

Deficiency Comments:

6 COMMENTS/CONSULTS FOR OTHER DISCIPLINES

(b) (4)



Andrew  
Choi

Digitally signed by Andrew Choi  
Date: 6/10/2024 12:07:12AM  
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Burhan  
Nour

Digitally signed by Burhan Nour  
Date: 6/10/2024 11:59:27AM  
GUID: 508da70600028ae6e75df33aa0f5b2ce

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209903Orig1s010**

**CHEMISTRY REVIEW(s)**

Disciplines Involved	Outcome	Disciplines Involved	Outcome
Chemistry	AC	Biopharmaceutics	NA
Microbiology	NA	Bioequivalence	NA
Facilities	AC	DMF (Chemistry)	NA
Labeling	AC	DMF (Microbiology)	NA
Submissions Assessed			
Received Date:	1/25/2024		
Amendment(s) Date:	07/08/2024 – IR Response		

**OFFICE OF PHARMACEUTICAL QUALITY**  
**ASSESSMENT OF SUPPLEMENT TO ABBREVIATED NEW DRUG APPLICATION**

**Chemistry Assessment Number** : 01

**ANDA/Supplement Number** : 209903/S-10

**Drug Product Name, Strength** : Diclofenac Sodium Topical Gel, 1% w/w

**Pharmacological Category/ Indication(s)** : Diclofenac sodium is a non-steroidal anti-inflammatory drug indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.

**Applicant Name (or US Agent if Applicable)** : Cipla Limited (US agent CIPLA USA, INC.)

**Supplement Provides For** : Full Prescription (Rx) to Over-The-counter (OTC) Switch & Addition of new drug product manufacturing facility (Bora Pharmaceutical Services Inc.; FEI: 3002807086; DUNS: 205556368).

**Filing Category with basis for decision/comments (based on guidance for industry/CFR quotes)** : PAS

**Relevant Supporting DMF(s) Cited (If Applicable)**

DMF No.	DMF	Result of Assessment	Date Assessment Completed
NA	Comment (if any) on DMF Assessment, Assessor		

## ASSESSMENT NOTES

Cipla Limited (Cipla) is proposing the following two changes:

1. Change the marketing category from Full prescription (Rx) to over-the-counter (OTC), to be in line with RLD, Voltaren arthritis pain, NDA N022122.
2. Addition of an Alternate Manufacturing Site, Bora Pharmaceutical Services Inc. (BPSI) FEI # 3002807086, for drug product manufacture.

On Feb 14, 2020, the RLD, Voltaren® arthritis pain (NDA #022122), was approved for a marketing status change from full prescription (Rx) to OTC. To be in line with the RLD, Cipla proposes the marketing status of its approved ANDA #209903, Diclofenac Sodium Topical Gel, 1% w/w, be changed from full prescription (Rx) to OTC.

Labeling information, including artwork, annotated labeling text, the final printed label, side by side comparison with the RLD, and copies of the labeling for the RLD, are provided in **Section 1.14**.

Cipla's proposed labeling for Diclofenac Sodium Topical Gel, 1% (NSAID) is in compliance with the format and content requirements set forth under 21 CFR 201.66 and with 21 CFR 211.132 (Tamper-evident packaging requirements for OTC human drug products).

Cipla proposes an alternate drug product manufacturing facility for Diclofenac Sodium Topical Gel, 1% w/w: Bora Pharmaceutical Services Inc. (Mississauga, Ontario, Canada; FEI: 3002807086; hereafter referred to as BPSI or Bora). (b) (4)

Currently, Cipla Limited, Unit III, Goa (Verna, Salcette, Goa, India; FEI:3004081307; hereafter referred to as Cipla Goa) (b) (4)

(b) (4) are the approved manufacturing sites for Diclofenac Sodium Topical Gel, 1% w/w.

(b) (4)

An Information Request was sent on 06/28/2024. The Applicant responded in an amendment received on 07/08/2024.

### **Drug Substance**

There is no change in the approved API manufacturers and Bora will continue to use API from the approved source – (b) (4).

The drug substance [specification](#) and analytical procedures remain the same as approved and are provided in **Sections 3.2.S.4.1** and **3.2.S.4.2**, respectively.



**RECOMMENDATION**

- Supplement is CMC Approvable
- Supplement is NOT CMC Approvable (with brief explanation:)

(Choose  IR,  CR-Minor,  CR-Major); Deficiencies noted below:

Deficiencies to be communicated:

**Primary Assessor : Maya K. Monroe, Ph.D.**

**Date : 07/10/2024**



Maya  
Monroe

Digitally signed by Maya Monroe  
Date: 7/10/2024 10:14:54AM  
GUID: 64146b660014c724ad4b860ad87ed853



Kylie  
Grainger

Digitally signed by Kylie Grainger  
Date: 7/10/2024 12:05:05PM  
GUID: 5315f9aa00007f6658b1659c21bdfd60

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209903Orig1s010**

**OTHER REVIEW(s)**

**CLINICAL CONSULTATION REVIEW**  
**Division of Clinical Review (DCR)**  
**Office of Safety and Clinical Evaluation (OSCE), Office of Generic Drugs (OGD)**  
**Center for Drug Evaluation & Research (CDER)**

<b>ANDA</b>	209903 Supplement-10
<b>Drug Product</b>	Diclofenac Sodium Topical Gel, 1%
<b>Reference Listed Drug (RLD)</b>	Voltaren Arthritis Pain (diclofenac sodium) Topical Gel, 1% NDA 022122
<b>Primary Clinical Reviewer</b>	Stephanie Soukup, MD Physician
<b>Secondary Clinical Reviewer</b>	Andrew Fine, PharmD Senior Advisor
<b>To</b>	Andrew Choi Division of Labeling Review
<b>Reason for Consult</b>	To determine if the applicant adequately addressed the previously issued comments in Supplement-6
<b>Date of Consult Request</b>	4/18/2024
<b>Date Assigned</b>	4/22/2024
<b>Date of Completion</b>	5/14/2024
<b>Conclusion</b>	DCR finds the user interface of the proposed drug-device combination product acceptable. The Applicant has adequately addressed the deficiencies from the 10/2/2020 Complete Response (CR) Letter.

## 1 Introduction and Background

This review serves as a response to a consultation from the Division of Labeling Review (DLR) for ANDA 209903 Supplement -10. ANDA 209903 for Diclofenac Sodium Topical Gel, 1% was initially approved on 8/3/2018 as a prescription product referencing NDA 022122 for Voltaren (diclofenac sodium) gel. Both products are supplied with a co-packaged dosing card. The RLD was initially approved on 10/17/2007 for prescription use, then on 2/14/2020 approved for over-the-counter (OTC). After RLD approval for OTC use, Cipla Ltd. (Applicant) submitted ANDA

(b) (4) submitted their response to the deficiencies issued by DCR in the current supplement (Supplement-10) submitted on 1/25/2024<sup>2</sup>.

<sup>1</sup> Panorama ANDA 209903. DCR CA review dated 8/19/2020.  
<https://panorama.fda.gov/document/view?ID=5f3d49d900ed76fe0c19e55b5c8439f1>

<sup>2</sup> Lorenz DocuBridge ANDA 209903 Supplement 10 dated 1/25/2024.  
<\\CDSESUB1\EVSPROD\anda209903\0049\m1\us\12-cover-letter\cover-letter-seq-0049.pdf>



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<sup>3</sup> Panorama ANDA 209903. DLR consult to DCR dated 4/18/2024.  
<https://panorama.fda.gov/document/view?ID=6621960e004ba38a7aee5b8b0cbc4d65>



**Proposed Generic Product Dosing Card (ANDA 209903, Supplement-10)**

**Dosing Card**  
**Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever**

Upper body dose 2.25 inches long (2 grams)

Lower body dose 4.5 inches long (4 grams)

Read product User Guide before use, Not for immediate pain relief.

98324756

**RLD (NDA 022122) updated on 2/14/20**

**Voltaren** ARTHRITIS PAIN  
 diclofenac sodium topical gel, 1% (NSAID) - arthritis pain reliever

**Dosing Card**

Upper body dose 2.25 inches long (2 grams)

Lower body dose 4.5 inches long (4 grams)

Read product User Guide before use  
 Not for immediate pain relief

A044671

**Reviewer's Comments:**

The Applicant's revised dosing card provides two distinct, labeled dosing lines indicating the upper and lower body doses which is consistent with the RLD. This reviewer identified the following differences:

- The proposed card includes an outlined image of a person with dots indicating the possible treatment areas whereas the RLD card does not.
- The proposed card dosing lines are outlined whereas the RLD has different solid colors filling each dosing line.

- *The name and instruction to “read product user guide before use, Not for immediate pain relief” differ in location on each card.*

**Comparative Task Analysis**

To use the RLD and proposed products, the user must (1) remove the cap, (2) pierce the safety seal, (3) squeeze the amount of gel onto the appropriate dosing line (upper or lower body dose), and (4) apply to the appropriate target area. After using the dosing card, both RLD and proposed cards are to be washed with soap and water in preparation for the next use.


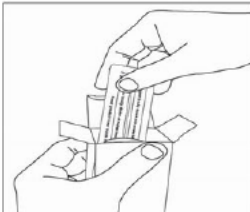
**Reviewer’s Comments:**

*There are no differences in the tasks to use the RLD and updated proposed device (dosing card). Although the shape of the cap is different in one configuration of the RLD, this does not affect a critical task because the user would use the same motion to remove the cap (twisting counterclockwise). The remaining physical differences in device (color/design and location of name and warning on dosing card) do not affect a user task and are therefore minor.*

**Labeling Comparison**

The Applicant submitted an updated labeling (including IFU and carton labels) within Supplement-10. Except for the delivery device-related part of labeling, the assessment of the remainder of the labeling is deferred to the Division of Labeling Review (DLR). The IFU and carton labels are shown below in Tables 2 and 3.

**Table 2: RLD and Updated Proposed Generic IFU**

RLD (NDA 022122)	Proposed Generic (ANDA 209903 Supplement-10)
<p><b>Voltaren</b> <b>ARTHRITIS PAIN</b> diclofenac sodium topical gel, 1% (NSAID) - arthritis pain reliever</p> <p>User Guide</p> <p>How to use <b>Voltaren Arthritis Pain</b>, with answers to frequently asked questions</p> <p>Quick Start</p> <p>How to get started right away with <b>Voltaren Arthritis Pain</b></p> <p>Understanding <b>Voltaren Arthritis Pain Gel</b></p> <p><b>Voltaren Arthritis Pain (diclofenac sodium topical gel, 1% (NSAID) - arthritis pain reliever)</b> is an arthritis pain relief medication that you apply to your skin. It is intended to be used 4 times a day every day for up to 21 days.</p> <p>Before You Use <b>Voltaren Arthritis Pain</b></p> <p>Read the Drug Facts Label, which appears on the carton.</p> 	<p><b>Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever</b></p> <p>User Guide</p> <p>How to use <b>Diclofenac Sodium Topical Gel (NSAID)</b>, with answers to frequently asked questions</p> <p>Quick Start</p> <p>How to get started right away with <b>Diclofenac Sodium Topical Gel (NSAID)</b></p> <p>Understanding <b>Diclofenac Sodium Topical Gel (NSAID)</b></p> <p><b>Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever</b> is an arthritis pain relief medication that you apply to your skin. It is intended to be used 4 times a day every day for up to 21 days.</p> <p>Before You Use <b>Diclofenac Sodium Topical Gel (NSAID)</b></p> <p>Read the Drug Facts Label, which appears on the carton.</p> 

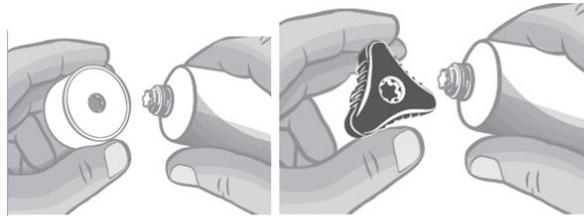
Remove the dosing card from the inside of the carton. You should always use the dosing card to measure out the correct dose of **Voltaren Arthritis Pain**.

The first time you use a tube of **Voltaren Arthritis Pain**:

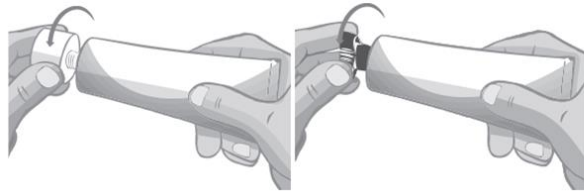
You will have **either one of** the caps shown below.



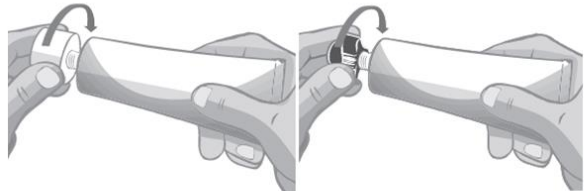
1. Take the cap off the tube. **Open** the safety seal by firmly pressing the **indent** on the top of the cap onto the **star-shaped** seal on the tube.



2. **Firmly turn the cap to remove the safety seal.** Do not open the safety seal with scissors or other sharp objects.



3. After use, put the cap back on the end of the tube.



**Using Voltaren Arthritis Pain**

**How often to use Voltaren Arthritis Pain**

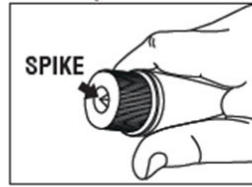
Use 4 times a day for best results.

For example:

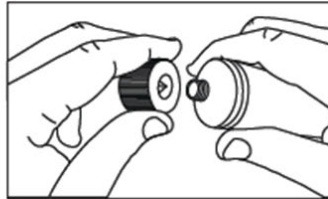
Remove the dosing card from the inside of the carton. You should always use the dosing card to measure out the correct dose of **Diclofenac Sodium Topical Gel (NSAID)**.

The first time you use a tube of **Diclofenac Sodium Topical Gel (NSAID)**:

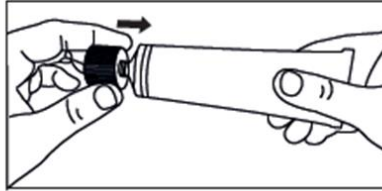
You will have the cap **as** shown below.



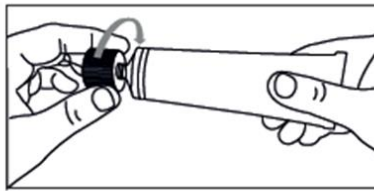
1. Take the cap off the tube.



2. **Open** the safety seal by firmly pressing the **spike** on the top of the cap onto the seal on the tube. Do not open the safety seal with scissors or other sharp objects.



3. After use, put the cap back on the end of the tube.

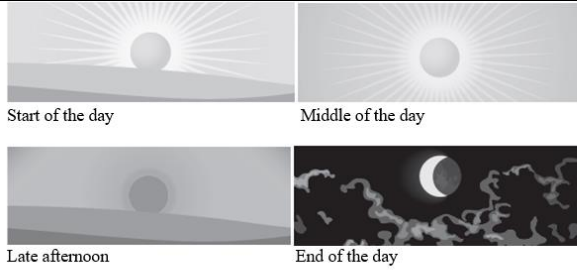


**Using Diclofenac Sodium Topical Gel (NSAID)**

**How often to use Diclofenac Sodium Topical Gel (NSAID)**

Use 4 times a day for best results.

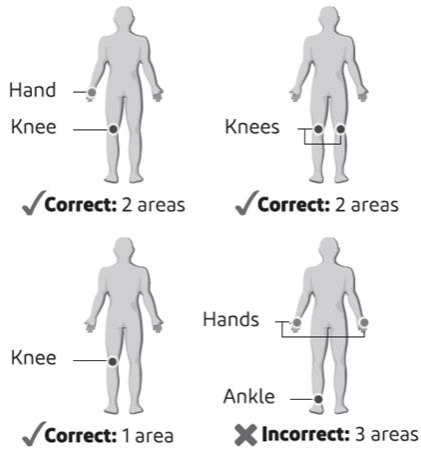
For example:



**Where to apply Voltaren Arthritis Pain**

**Voltaren Arthritis Pain** can be used on up to 2 body areas from the following list: a hand, a wrist, an elbow, a foot, an ankle, a knee. Do not use on more than 2 body areas at once.

Some examples include:



**Measuring the correct amount using the dosing card**



**For each upper body area** (a hand, a wrist, or an elbow): Squeeze gel from the tube equal to the length shown on the upper body section of the dosing card (2.25 inches).

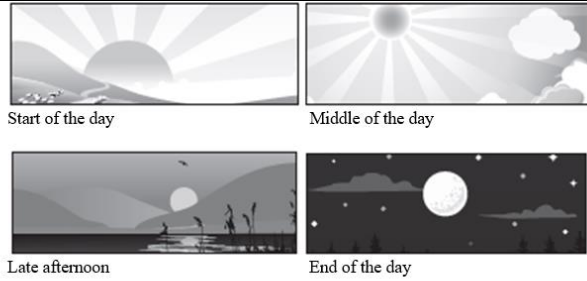


**For each lower body area** (a foot, an ankle, or a knee): Squeeze gel from the tube equal to the length shown on the lower body section of the dosing card (4.5 inches).

**Applying Voltaren Arthritis Pain**

Gently rub **Voltaren Arthritis Pain** into the skin using your hand. Apply 4 times a day for best results. Do not use on more than 2 body areas at once.

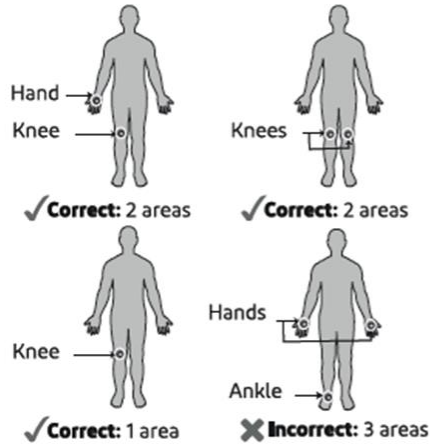
Apply only to clean, dry skin that doesn't have any cuts, open wounds, infections or rashes. Do not apply in the same area as any other medicines or products that are applied to the skin.



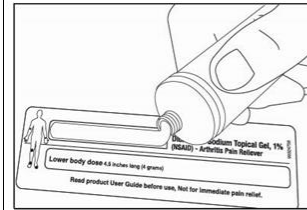
**Where to apply Diclofenac Sodium Topical Gel (NSAID)**

**Diclofenac Sodium Topical Gel (NSAID)** can be used on up to 2 body areas from the following list: a hand, a wrist, an elbow, a foot, an ankle, a knee. Do not use on more than 2 body areas at once.

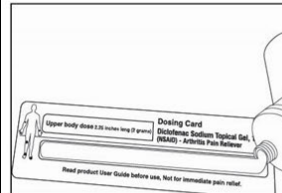
Some examples include:



**Measuring the correct amount using the dosing card**



**For each upper body area** (a hand, a wrist, or an elbow): Squeeze gel from the tube equal to the length shown on the upper body section of the dosing card (2.25 inches).



**For each lower body area** (a foot, an ankle, or a knee): Squeeze gel from the tube equal to the length shown on the lower body section of the dosing card (4.5 inches).

**Applying Diclofenac Sodium Topical Gel (NSAID)**

Gently rub **Diclofenac Sodium Topical Gel (NSAID)** into the skin using your hand. Apply 4 times a day for best results. Do not use on more than 2 body areas at once.

Apply only to clean, dry skin that doesn't have any cuts, open wounds, infections or rashes. Do not apply in the same area as any other medicines or products that are applied to the skin.

**Upper body areas**



**Elbow**  
Including sides, inner, and outer



**Wrist**  
Including sides, top, and bottom



**Hand**  
Including top, palm, and fingers

**Lower body areas**



**Knee**  
Including sides, kneecap, and back



**Ankle**  
Including sides, front, and back



**Foot**  
Including sole, top of foot, and toes

After You Use **Voltaren Arthritis Pain**



Wash your hands after applying **Voltaren Arthritis Pain**. If the treated area is the hands wait up to 1 hour to wash the hands.



Wash the dosing card with water. Store dosing card with your **Voltaren Arthritis Pain** and keep out of reach of children.

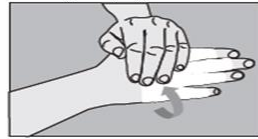
**Upper body areas**



**Elbow**  
Including sides, inner, and outer



**Wrist**  
Including sides, top, and bottom



**Hand**  
Including top, palm, and fingers

**Lower body areas**



**Knee**  
Including sides, kneecap, and back

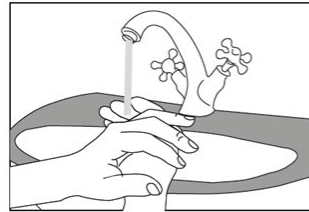


**Ankle**  
Including sides, front, and back

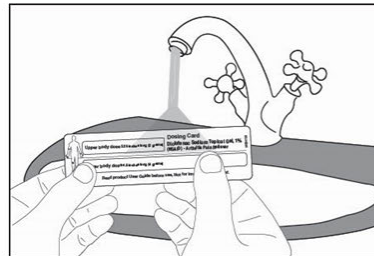


**Foot**  
Including sole, top of foot, and toes

After You Use **Diclofenac Sodium Topical Gel (NSAID)**


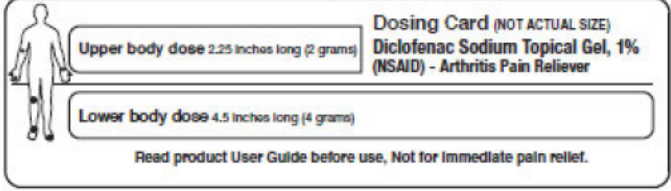






Wash your hands after applying **Diclofenac Sodium Topical Gel (NSAID)**. If the treated area is the hands wait up to 1 hour to wash the hands.



Wash the dosing card with water. Store dosing card with your **Diclofenac Sodium Topical Gel (NSAID)** and keep out of reach of children.

**Table 3: RLD and Proposed Generic Carton Labels**

Proposed Generic Product Dosing Card (ANDA 209903, Supplement-10)					
<p><b>Drug Facts (continued)</b></p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> Use up to 21 days unless directed by your doctor. Not for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Daily</th> <th style="text-align: center;">Per Dose</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">                     For your arthritis pain:                      • Use 4 times per day every day                      • Do not use on more than 2 body areas at the same time                 </td> <td style="padding: 2px;">                     Use ENCLOSED DOSING CARD to measure a dose                      • For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams)                      • For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)                 </td> </tr> </tbody> </table>	Daily	Per Dose	For your arthritis pain: • Use 4 times per day every day • Do not use on more than 2 body areas at the same time	Use ENCLOSED DOSING CARD to measure a dose • For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams) • For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)	<p><b>Drug Facts (continued)</b></p> <p>Read the enclosed User Guide for complete instructions:</p> <ul style="list-style-type: none"> <li>• Use only as directed</li> <li>• do not use more than directed or for longer than directed</li> <li>• apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes</li> <li>• do not apply in same area as any other product</li> <li>• do not apply with external heat such as heating pad</li> <li>• do not apply a bandage over the treated area</li> <li>• store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel, 1%. The dosing card is re-usable.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• store at 20°C to 25°C (68°F to 77°F). Keep from freezing.</li> <li>• read all product information before using.</li> <li>Keep the dosing card, this carton and accompanying User Guide for important information.</li> </ul> <p><b>Inactive ingredients:</b> carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 tectoacryl ether, propylene glycol, purified water, strong ammonia solution</p> <p>Questions or comments? 1-866-604-3268</p>
Daily	Per Dose				
For your arthritis pain: • Use 4 times per day every day • Do not use on more than 2 body areas at the same time	Use ENCLOSED DOSING CARD to measure a dose • For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams) • For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)				
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="background-color: #e91e63; color: white; padding: 5px 10px; font-weight: bold;">NEW</div> <div style="background-color: #393b79; color: white; padding: 5px 20px; font-weight: bold;">ORIGINAL PRESCRIPTION STRENGTH</div> <div style="color: #393b79; font-weight: bold; font-size: 1.2em;">Cipla</div> </div> <p style="text-align: center; margin-top: 10px;">NDC 69097-720-44</p> <h2 style="text-align: center; margin: 0;">Diclofenac Sodium Topical Gel, 1%</h2> <p style="text-align: center; margin: 0;">(NSAID) - Arthritis Pain Reliever</p> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;"> <p>For Daily Treatment of Arthritis Pain</p> <p>Anti-inflammatory</p> </div> <div style="text-align: center;"> <p>For external use only</p> <p>NET WT 100 g (3.53 oz)</p> </div>  </div>					
<p><b>Use Enclosed Dosing Card to Measure a Dose</b></p> <div style="display: flex; align-items: center; justify-content: center;">  <div style="margin-left: 20px;"> <p><b>Dosing Card (NOT ACTUAL SIZE)</b> Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever</p> <p>Read product User Guide before use, Not for immediate pain relief.</p> </div> </div>					
<p><b>Medicated Gel Clinically Proven to Relieve Arthritis Pain</b></p> <p><b>TREATMENT AREAS</b></p> <div style="display: flex; justify-content: center; gap: 20px;"> <div style="text-align: center;">  Hand         </div> <div style="text-align: center;">  Wrist         </div> <div style="text-align: center;">  Elbow         </div> </div> <div style="display: flex; justify-content: center; gap: 20px; margin-top: 10px;"> <div style="text-align: center;">  Foot         </div> <div style="text-align: center;">  Ankle         </div> <div style="text-align: center;">  Knee         </div> </div> <p style="text-align: center; font-size: 0.8em;">Not for use on any other body area (such as back, hip, or shoulder)</p>					
<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Diclofenac sodium (NSAID*) 1% (equivalent to 0.93% diclofenac) ..... Arthritis pain reliever *nonsteroidal anti-inflammatory drug</p> <p><b>Purpose</b> Arthritis pain reliever</p> <p><b>Uses</b> • for the temporary relief of arthritis pain ONLY in the following areas: • hand, wrist, elbow (upper body areas) • foot, ankle, knee (lower body areas) • this product may take up to 7 days to work for arthritis pain; it is not for immediate relief. If no pain relief in 7 days, stop use.</p> <p><b>Warnings</b> For external use only. Allergy alert: Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • hives • asthma (wheezing) • skin reddening • blisters • facial swelling • shock • rash If an allergic reaction occurs, stop use and seek medical help right away. Liver warning: This product contains diclofenac. Liver damage may occur if you apply more or for a longer time than directed • when using other drugs containing diclofenac Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while using this product • apply more or for longer than directed</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p> <p><b>Do not use</b> • if you have ever had an allergic reaction to any other pain reliever or to a fever reducer • for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries. • right before or after heart surgery • on more than 2 body areas at the same time • in the eyes, nose or mouth</p> <p><b>Ask a doctor before use if</b> • you have problems or serious side effects from taking pain relievers or fever reducers • stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • you are taking a diuretic • you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.</p> <p><b>Ask a doctor or pharmacist before use if you are</b> • under a doctor's care for any serious condition • taking any other drug</p> <p><b>When using this product</b> • avoid contact with eyes, nose, or mouth • if eye contact occurs, rinse thoroughly with water</p> <p><b>Stop use and ask a doctor if</b> • pain gets worse or lasts more than 21 days • redness or swelling is present in the painful area • fever occurs • skin irritation occurs • any new symptoms appear. These could be signs of a serious condition. • you experience any of the following signs of stomach bleeding: • feel faint • have bloody or black stools • vomit blood • have stomach pain that does not get better • you have symptoms of heart problems or stroke: • chest pain • trouble breathing • leg swelling • weakness in one part or side of body • slurred speech</p>				



*they describe and reflect the differences in device.*

### **3 Conclusion**

From a clinical safety perspective, there are minor design differences between the RLD and updated proposed drug delivery device (dosing card color, dosing card product name and placement, IFU images and artwork). Therefore, DCR concludes this generic combination product can be substituted for the RLD without the intervention of a health care provider and/or without additional training prior to use of the generic combination product and that the design differences as compared to RLD do not alter the clinical effect or safety profile of this proposed ANDA product under the conditions of use as specified in the labeling. In summary, DCR finds the proposed drug device user interface for the proposed generic acceptable. The Applicant has adequately addressed the deficiencies related to the proposed drug device in the 10/2/2020 CR letter.

#### DLR Consult Question:

From DCR's perspective, has the applicant adequately addressed the previously issued comments?

#### DCR Answer:

The Applicant has adequately addressed the deficiencies related to the user interface of the proposed drug-device combination product in the 10/2/2020 CR letter.



Stephanie  
Soukup

Digitally signed by Stephanie Soukup  
Date: 5/14/2024 11:51:39AM  
GUID: 5b4df125005190ade6393d66c1219bcc



Andrew  
Fine

Digitally signed by Andrew Fine  
Date: 5/14/2024 12:52:15PM  
GUID: 50174afb000001af8e1e5e9e9cb6265d

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209903Orig1s010**

**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**

Approval Type:  FULL APPROVAL  TENTATIVE APPROVAL  SUPPLEMENTAL AP or TA (Rx to OTC)

RPM and TL: **Sarah Nguyen and Surjit Basi**

ANDA #: **209903/S-010** Applicant: **Cipla Limited**  
 Established Product Name: **Diclofenac Sodium Topical Gel, 1% (OTC)**

Basis of Submission (BOS)/RLD (Application#/Proprietary Name/Applicant): **N022122; Voltaren Arthritis Pain Gel; Haleon US Holdings LLC**

If BOS discontinued: [\[insert hyperlink to FRN\]](#)  Safety/effectiveness FRN pending

**Select, as applicable:**

- RX  OTC
- History of tentative or split approval action
- Shared Bio Studies (list ANDA number(s) \_\_\_\_\_)  Shared Labeling (list ANDA number(s) \_\_\_\_\_)
- Memo uploaded for PAL item or OGD confirmation
- Priority:  First Generic Approval (i.e., no other generics approved)  Drug Shortage  PEPFAR  CGT
- Other priority \_\_\_\_\_
- Misc:  REMS  Combination product  Suitability Petition  180-day language  MOU  PEPFAR

**RPM Has Verified the Following:** **Date: 7/10/2024**

1. ANDA number, NDA/RLD, Drug product and strength(s) are correct on all discipline/subdiscipline reviews
2. All submissions have been reviewed: Relevant disciplines are adequate and finalized/archived in the appropriate system of record
3. Most recent BE guidance is included in the review or a memo has been uploaded
4. No RLD updates or changes to exclusivity/patents impact endorsed labeling
5. All amendments submitted to the Agency on or after December 5, 2016 contain (1) a patent certification or section viii statement, (2) a recertification, or (3) a verification statement per 21 CFR 314.96(d). (Not applicable to supplements)
6. OSIS Clinical Endpoint and Bioequivalence Site Inspections acceptable or not applicable
7. No blocking legal or regulatory issue (refer to Policy Alert Tracker)
8. OGD Communications has been notified if Priority Approval (First generic, Drug Shortage, PEPFAR, CGT, other OGD Communications priorities)
9. OMIR is Approve with no new facility alerts and a DP and API manufacturer listed in Submission Facility Status View
10. No open issues or tasks in Platform
11. No pending consults
12. Filing review completed for NSA or reformulation
13. PNR review is current
14. Correct language, format and content in action letter (e.g., relevant contact from 356h form)
15. Endorsements are within 29 days

Discipline Completion Dates:

Bioequivalence <b><u>n/a</u></b>  Labeling <b><u>6/10/2024</u></b>  Clinical Bioequivalence <b><u>5/14/2024</u></b>  Combination Product Comparative Analysis <b><u>n/a</u></b>	Integrated Quality Assessment: <b><u>n/a</u></b> If there is no IQA, provide the applicable date(s): <ul style="list-style-type: none"> <li>• Chemistry <b><u>7/10/2024</u></b></li> <li>• Microbiology n/a</li> <li>• Biopharmaceutics/Dissolution n/a</li> </ul> DMF No(s). n/a Date(s) Acceptable n/a
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**Additional Notes (if applicable)**

**ANDA APPROVAL ROUTING SUMMARY ENDORSEMENTS AND FINAL DECISION**

**1. Division of Legal and Regulatory Support Endorsement**

Date: 7/15/2024

Name: IM

<p><b>Patent/Exclusivity Certification:</b>  <input type="checkbox"/> No Relevant Patents <input checked="" type="checkbox"/> PI <input type="checkbox"/> PII <input type="checkbox"/> PIII <input type="checkbox"/> PIV <input type="checkbox"/> section viii</p> <p>Reminders:</p> <ul style="list-style-type: none"> <li>- Check the policy alert list for any pending exclusivity determinations</li> <li>- Verify in the Orange Book there are no unexpired ODE's that cover the active moiety</li> <li>- Confirm the ANDA is not blocked by other ANDA's eligibility for 180-day CGT exclusivity</li> <li>- Confirm S/E determination completed for RLDs in the discontinued section of the OB</li> </ul>	<p>RLD = <u>Voltaren Gel</u> NDA# <u>22122</u> <input type="checkbox"/> RX or <input checked="" type="checkbox"/> OTC  Date Checked in Orange Book#: <u>7/15/2024</u></p> <p><b>Type of Letter:</b>  <input type="checkbox"/> APPROVAL  <input type="checkbox"/> TENTATIVE APPROVAL  <input checked="" type="checkbox"/> SUPPLEMENTAL AP or TA (NEW STRENGTH)</p>
<p><b>Forfeiture Information</b></p> <ul style="list-style-type: none"> <li>- Confirm whether the first applicant remains eligible for 180-day exclusivity (i.e., that a forfeiture event under section 505(j)(5)(D) has not occurred) and document the determination</li> </ul> <p>Is a forfeiture memo needed for the first applicant: Yes <input type="checkbox"/> No <input type="checkbox"/>  If yes, the date forfeiture memo was completed  Date _____ ANDA # _____</p> <p><b>Competitive Generic Therapy 75 Day Special Forfeiture Rule:</b>  First Applicant: ANDA # _____  Date of Approval: _____  75 Day Date: _____</p>	<p><b>180 Day Exclusivity Information</b></p> <p>Is applicant eligible for H-W 180 day exclusivity Yes <input type="checkbox"/> No <input type="checkbox"/>  <input type="checkbox"/> Sole  <input type="checkbox"/> Shared</p> <p>Is applicant eligible for CGT 180 day exclusivity Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>  <input type="checkbox"/> Sole  <input type="checkbox"/> Shared</p> <p>Is applicant blocked by a triggered CGT 180 day exclusivity  Yes <input type="checkbox"/> No <input type="checkbox"/>  If no, the date and time checked for notification of commercial marketing: Date _____ Time: _____</p>

Comments:  
BOS = Voltaren Gel (NDA 22122) Application submission 12/29/2016 for the Rx version of the drug product with a PI certification. Acknowledgment letter signed 2/24/2017.

ANDA received full approval 8/3/2018.

NDA 22122 was approved 2/14/2020 to full OTC switch from Rx under the name Volatern Arthritis Pain.

Cipla submitted a PAS 1/25/2024 to also switch their approved Rx ANDA to OTC. This switch is a simple label change supplement due to no changes in the approved ANDA drug product formulation or manufacturing, and there remains no unexpired patents or exclusivities listed in the OB to the NDA.

Cipla's PAS to convert their previously approved Rx product to OTC is eligible for Full Approval.

Food and Drug Administration CDER / Office of Generic Drugs	Document No.: 30051	Version: 6.0
<b>Document Status: APPROVED</b>		
<b>Title:</b> Approval Routing Summary Form	<b>Author:</b> Kevin Denny	

180 Day/CGT Exclusivity Status/Landscape: N/A  
 If known, impact on pending exclusivity determinations: N/A  
 If Tentative Approval, if known, anticipated full approval date: N/A

**2. Final Decision**

**Date:** 7/15/2024  
**Name:** CAP

Verified the following:

1. Completion of the following endorsement tasks, if applicable:
  - a. Division of Legal and Regulatory Support Endorsement
  - b. Paragraph IV Evaluation
  - c. REMS Endorsement
  - d. Quality Endorsement
  - e. Bioequivalence Endorsement
  - f. Clinical-Bioequivalence Endorsement
  - g. Labeling Endorsement
  - h. RPM Team Leader Endorsement
2. All applicable endorsement tasks are completed in the platform within 30 days of potential approval.
3. No updates to patents and/or exclusivities in Orange Book since the Division of Legal and Regulatory Support Endorsement
4. No Reference Listed Drug updates in DARRTS since the Labeling Endorsement
5. No new issues listed on the current version of the Policy alert list since the RPM Team Leader Endorsement
6. No new alerts in the Submission Facility Status View since the Quality Endorsement
7. Overall Inspection Recommendation of Approve of the current project (see screenshot below)
8. No new DMF amendments received since Quality Endorsement
9. No new amendments received since the RPM Team Leader Endorsement

This **ANDA** is ready for **FULL APPROVAL**.

**\*\*\*INCLUDE SNIP OF SUBMISSION FACILITY STATUS VIEW AT THE TIME OF APPROVAL\*\*\***



Food and Drug Administration CDER / Office of Generic Drugs	Document No.: 30051	Version: 6.0
<b>Document Status: APPROVED</b>		
<b>Title:</b> Approval Routing Summary Form	<b>Author:</b> Kevin Denny	

(b) (4)



<i>Originating Office: Office of Regulatory Operations (ORO)</i>	<i>Effective Date: 2021-10-06</i>	Page 4 of 6
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Please ensure you are using the most current version of this Form, available at:  
OGD Controlled Documents Program Library - <http://ogd.fda.gov/QDoc/Library/Index>

Food and Drug Administration CDER / Office of Generic Drugs	Document No.: 30051	Version: 6.0
<b>Document Status: APPROVED</b>		
Title: Approval Routing Summary Form	Author: Kevin Denny	

Endorsement Signatures (To be provided by endorsees in the event of Platform unavailability):

- Division of Legal and Regulatory Support Endorsement
  - Sign & Date \_\_\_\_\_
- Paragraph IV Evaluation
  - Sign & Date \_\_\_\_\_
- REMS Endorsement
  - Sign & Date \_\_\_\_\_
- Quality Endorsement
  - Sign & Date \_\_\_\_\_
- Bioequivalence Endorsement
  - Sign & Date \_\_\_\_\_
- Clinical-Bioequivalence Endorsement
  - Sign & Date \_\_\_\_\_
- Labeling Endorsement
  - Sign & Date \_\_\_\_\_
- RPM Team Leader Endorsement
  - Sign & Date \_\_\_\_\_
- ORO IO Endorsement
  - Sign & Date \_\_\_\_\_

<i>Originating Office: Office of Regulatory Operations (ORO)</i>	<i>Effective Date: 2021-10-06</i>	Page 5 of 6
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Food and Drug Administration CDER / Office of Generic Drugs	Document No.: 30051	Version: 6.0
<b>Document Status: APPROVED</b>		
<b>Title:</b> Approval Routing Summary Form	<b>Author:</b> Kevin Denny	

#### REFERENCES / ASSOCIATED DOCUMENTS

Reference Name
4000-LPS-041 Processing Approval and Tentative Approval of an Original ANDA

#### REVISION HISTORY

Author	Role	Version	Change Date	Summary of Changes
Heather Strandberg	Author	1.0	2014-10-01	New Form
Kevin Denny	Reviser	2.0	2017-10-03	Update form to reflect revisions to SOP 4000-LPS-041 Processing Approval and Tentative Approval of an Original ANDA, Version 04 Remove content adequately captured in the platform Update information captured in the Division of Legal and Regulatory Support Endorsement section Other minor administrative corrections to format and content
Kevin Denny	Reviser	3.0	2018-01-14	Update Final Decision section
Joe Shin	Reviser	4.0	2019-03-04	Changes made: 1) "No Relevant Patents" checkbox added to patent types; 2) Basis of Submission was updated to include (NDA#/Proprietary Name/Applicant); 3) Removed "(CR)" from the second checkbox in the RPM Evaluation section; 4) Added "Shared BE studies..." and "Shared Labeling..." bullets to the review date section; 5) Added a not applicable checkbox for the MMA question; 6) Sentence revised to include not applicable cases in the OSIS question
John Ibrahim/QM Team	Reviser/QM	5.0	2021-08-18	<ul style="list-style-type: none"> <li>Update page 1 (revised ANDA information section, RPM checklist, and discipline completion dates)</li> <li>QM Team updated Header, document #, &amp; title to conform to OGD Controlled Documents Program naming conventions &amp; formatting standards</li> <li>QM Team updated Footer to conform to ISO 8601 – International Time &amp; Date Standards</li> </ul>



ANDA 209903/S-010

**INFORMATION REQUEST  
QUALITY**

Cipla USA, Inc.  
U.S. Agent for: Cipla Limited  
10 Independence Boulevard, Suite 300  
Warren, NJ 07059  
Attention: Michele Crawley  
Director - Regulatory Affairs

Dear Michele Crawley:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on January 25, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Diclofenac Sodium Topical Gel, 1% w/w.

We are reviewing the Quality section of your submission and have the following comments and information requests:

(b) (4)

We request a prompt written response, no later than July 5, 2024, in order to continue our evaluation of your ANDA. We will not process or review a partial response. Facsimile or e-mail responses will also not be accepted. In addition, if your response contains either gratuitous information not requested by FDA or information that requires a more thorough review as determined by FDA, FDA may classify the response as an amendment and assign an appropriate goal date for that amendment. The goal date assigned to the amendment may extend the review goal date for your current submission.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

**INFORMATION REQUEST  
QUALITY**

If you have any questions, please contact Jeena Amaya, Regulatory Business Process Manager, at [jeena.amaya@fda.hhs.gov](mailto:jeena.amaya@fda.hhs.gov) or (301) 796 - 9192.

Sincerely,

*{See appended electronic signature page}*

Jeena Amaya, MPAS  
Regulatory Business Process Manager  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration



Jeena  
Amaya

Digitally signed by Jeena Amaya

Date: 6/28/2024 10:45:26AM

GUID: 651d858d00e693589f28a63022f4027a

# REQUEST FOR CONSULTATION

TO (Division/Office):

**Mail: Division of Clinical Review (DCR)**

(If you know who the PM/Reviewer is please add them as a signer in DARRTS)

FROM:

**Andrew Choi, Division of Labeling Review (DLR)**

DATE 4/17/24	ANDA NO. 209903/S-010	TYPE OF DOCUMENT (Choose One) <input type="checkbox"/> ORIGINAL ANDA <input checked="" type="checkbox"/> SUPPLEMENT TO ANDA (S-010)	DATE OF DOCUMENT: 4/17/24
NAME OF DRUG <b>Diclofenac Sodium Topical Gel, 1%</b>	PRIORITY CONSIDERATION (Choose One) <input checked="" type="checkbox"/> GDUFA Due Date (HIGH) <input type="checkbox"/> Low	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE (Choose One) GDUFA Due Date: 7/25/24 Requested Due Date: 5/15/24

NAME OF FIRM:

## REASON FOR REQUEST

### I. GENERAL

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> NEW PROTOCOL                  | <input type="checkbox"/> PRE--NDA MEETING        | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER                         |
| <input type="checkbox"/> PROGRESS REPORT               | <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> FINAL PRINTED LABELING                                |
| <input type="checkbox"/> NEW CORRESPONDENCE            | <input type="checkbox"/> RESUBMISSION            | <input checked="" type="checkbox"/> LABELING REVISION (carton/container label) |
| <input type="checkbox"/> DRUG ADVERTISING              | <input type="checkbox"/> SAFETY/EFFICACY         | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE                           |
| <input type="checkbox"/> ADVERSE REACTION REPORT       | <input type="checkbox"/> PAPER NDA               | <input type="checkbox"/> FORMULATIVE REVIEW                                    |
| <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION | <input type="checkbox"/> CONTROL SUPPLEMENT      | <input type="checkbox"/> OTHER (SPECIFY BELOW):                                |
| <input type="checkbox"/> MEETING PLANNED BY            |  |  |

### II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):	<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):

### III. BIOPHARMACEUTICS

- |  |   |
|--|---|
| <input type="checkbox"/> DISSOLUTION             | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS  |
| <input type="checkbox"/> PHASE IV STUDIES        | <input type="checkbox"/> IN-VIVO WAIVER REQUEST     |

### IV. DRUG EXPERIENCE

- |  |  |
|--|--|
| <input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL             | <input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY |
| <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES | <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE                       |
| <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below)         | <input type="checkbox"/> POISON RISK ANALYSIS                                |
| <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP       |  |

### V. SCIENTIFIC INVESTIGATIONS

CLINICAL

PRECLINICAL

#### COMMENTS/SPECIAL INSTRUCTIONS:

DCR performed a Comparative (Threshold) Analyses for Drug-Device Combination Products for the subject ANDA 209903, [REDACTED] (b) (4)

4. Comments from the previous Comparative Analyses are copied below for reference. From DCR's perspective, has the applicant adequately addressed the previously issued comments?

1. Revise your dosing card to incorporate separate, clearly labeled dosing strip lines (Upper Body and Lower Body Doses) to more closely resemble the OTC RLD dosing card and submit an image of the updated dosing card.
2. Modify all dosing card images within the product label and packaging such as the User Guide to reflect the revised dosing card. Updated labeling including the User Guide should be submitted for review.

SIGNATURE OF REQUESTER Andrew Choi	METHOD OF DELIVERY (Check one) <input type="checkbox"/> MAIL <input type="checkbox"/> HAND <input type="checkbox"/> DAARTS <input checked="" type="checkbox"/> PANORAMA
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

Appears This Way  
On Original



Carol  
Lee

Digitally signed by Carol Lee

Date: 4/18/2024 05:53:14PM

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