BERKLEY AND JENSEN ARTHRITIS PAIN- diclofenac sodium BJWC

BJWC ARTHRITIS PAIN Drug Facts

Active ingredient

Diclofenac sodium (NSAID*) 1% (equivalent to 0.93% diclofenac)

*nonsteroidal anti-inflammatory drug

Purpose

Arthritis pain reliever

Uses

- for the temporary relief of arthritis pain <u>ONLY in</u> 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

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

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 (1-800-222-1222).

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 ENCLOSED DOSING CARD to measure a		
 Use 4 times per day every day Do not use on more than 2 body areas at the same time 	 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) 		

Read the enclosed <u>User Guide</u> 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%

product. The dosing card is re-usable.

Other information

- store at 20-25°C (68-77°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?

1-800-934-1204

Consumer Information

Diclofenac Sodium Topical Gel, 1% (NSAID)

Arthritis Pain Reliever

User Guide

How to use Diclofenac Sodium Topical Gel, 1% with answers to frequently asked questions

Quick Start

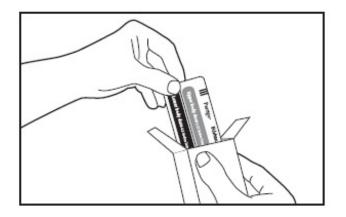
How to get started right away with Diclofenac Sodium Topical Gel, 1%

Understanding Diclofenac Sodium Topical Gel, 1%

Diclofenac Sodium Topical Gel, 1% **(NSAID)** – arthritis pain reliever is an arthritis pain relief medication that you apply to your skin.

Before You Use Diclofenac Sodium Topical Gel, 1%

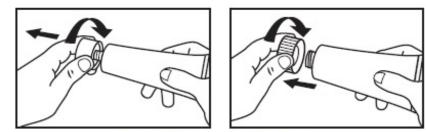
Read the Drug Facts Label, which appears on the carton.



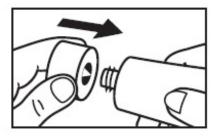
Remove the dosing card from the inside of the carton. You should always use the dosing card to measure out the correct dose of Diclofenac Sodium Topical Gel, 1%.

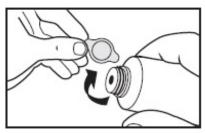
The first time you use a tube of Diclofenac Sodium Topical Gel, 1%:

You will have either one of the tube caps shown below



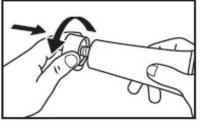
1. Take the cap off the tube.

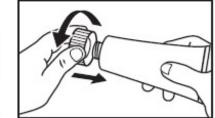




 Open the safety seal by firmly pressing the point on the top of the cap onto the seal on the tube. Do not open the safety seal with scissors or other sharp objects.

Open the safety seal by lifting and pulling the foil tab to remove foil safety seal from 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, 1% How often to use Diclofenac Sodium Topical Gel, 1%

Use 4 times a day for best results.

For example:



Start of the day



Middle of the day



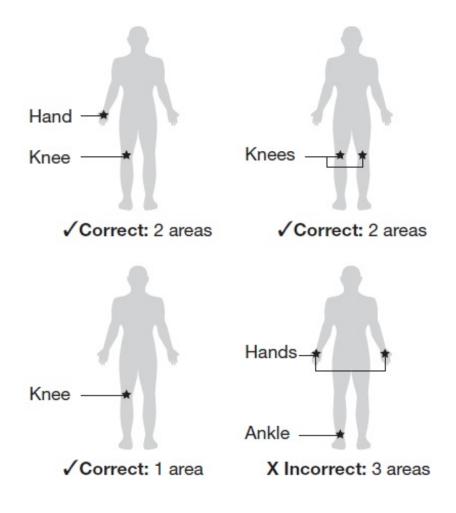
Late afternoon

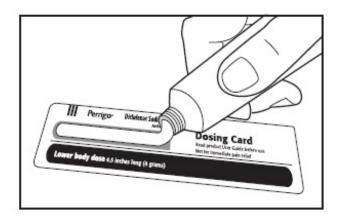
End of the day

Where to apply Diclofenac Sodium Topical Gel, 1%

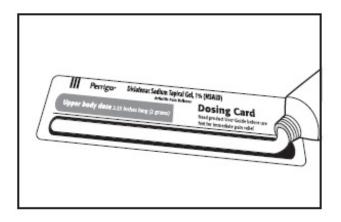
Diclofenac Sodium Topical Gel, 1% can be used on up to 2 body areas from the following list: a hand, a wrist, an elbow, a foot, an ankle, a knee. Do not use on more than 2 body areas at once.

Some examples include:





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 1-800-719-9260 to get a free replacement.

Applying Diclofenac Sodium Topical Gel, 1%

Gently rub Diclofenac Sodium Topical Gel, 1% 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

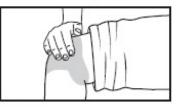


Wrist Including sides, top, and bottom



Hand Including top, palm, and fingers

Lower body areas



Knee Including sides, kneecap, and back

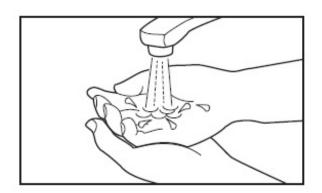


Ankle Including sides, front, and back

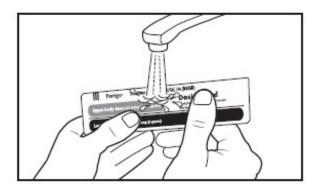


Foot Including sole, top of foot, and toes

After You Use Diclofenac Sodium Topical Gel, 1%



Wash your hands after applying Diclofenac Sodium Topical Gel, 1%. 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, 1% 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, 1%

Do not use Diclofenac Sodium Topical Gel, 1%...

- 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

Turn over for more information \rightarrow

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, 1%...

- 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 the 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, 1%. 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 (1-800-222-1222).

Stop using Diclofenac Sodium Topical Gel, 1% 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

Questions and Answers

Answers to questions you may ask about Diclofenac Sodium Topical Gel, 1%

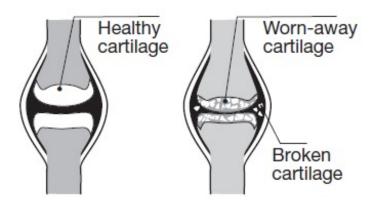
Can I use Diclofenac Sodium Topical Gel, 1% for the immediate relief of pain like that associated with sprains, strains, bruises, or sports injuries? Do not use for strains, sprains, bruises, or sports injuries. This product has not been shown to work for these types of injuries. It's intended only for the temporary relief of arthritis pain.

How quickly will Diclofenac Sodium Topical Gel, 1% work for arthritis pain?

Diclofenac Sodium Topical Gel, 1% 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, 1% used for?

Diclofenac Sodium Topical Gel, 1% 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, 1% work?

Diclofenac sodium, the medicine in Diclofenac Sodium Topical Gel, 1%, is a nonsteroidal anti-inflammatory drug (NSAID). NSAIDs are used to treat pain from medical conditions such as arthritis. Diclofenac Sodium Topical Gel, 1% 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, 1% 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, 1% differ from prescription Diclofenac Sodium Topical Gel, 1%?

Over-the-counter Diclofenac Sodium Topical Gel, 1% is the same strength and formula as original full prescription strength Diclofenac Sodium Topical Gel, 1% but is available without a prescription.

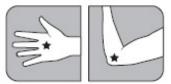
Apply Diclofenac Sodium Topical Gel, 1% 4 times a day to ensure you get the full effect of the medicine.

Can I apply Diclofenac Sodium Topical Gel, 1% to upper and lower body areas at the same time?

Yes.

You can use Diclofenac Sodium Topical Gel, 1% 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



Upper/Lower body Wrist and ankle



Lower body Knee and ankle



Lower body (L)Knee and (R)knee

Do not use Diclofenac Sodium Topical Gel, 1% on more than 2 body areas at once.

Can I apply Diclofenac Sodium Topical Gel, 1% 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, 1% on my spine, hips, or shoulders?

No.

The use of Diclofenac Sodium Topical Gel, 1% on the spine, hips, and shoulders has not been studied.

Can I take any other pain medications with Diclofenac Sodium Topical Gel, 1%?

Ask your doctor or pharmacist before using Diclofenac Sodium Topical Gel, 1% 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, 1%? 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, 1%.

How long can I use Diclofenac Sodium Topical Gel, 1%?

Use Diclofenac Sodium Topical Gel, 1% 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, 1% 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, 1% into a complete program to help manage your arthritis pain.

What do I do if I get Diclofenac Sodium Topical Gel, 1% 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, 1%?

If you forget to apply Diclofenac Sodium Topical Gel, 1% don't double your dose. Just apply the next dose as scheduled.

How should I store Diclofenac Sodium Topical Gel, 1%?

- Store at 20-25°C (68-77°F).
- Do not freeze Diclofenac Sodium Topical Gel, 1%.
- Store the dosing card with your Diclofenac Sodium Topical Gel, 1%.
- Keep out of reach of children.

Additional Questions?

Call 1-800-719-9260.

Made in Israel

Distributed By

Perrigo®

Allegan, MI 49010

87A00 00 J3

Package/Label Principal Display Panel

Compare to the active ingredient in Voltaren[®] Arthritis Pain

 $berkley jensen_{\mathbb{R}}$

ORIGINAL PRESCRIPTION STRENGTH

FOR EXTERNAL USE ONLY FOR DAILY TREATMENT OF ARTHRITIS PAIN ANTI-INFLAMMATORY ARTHRITIS PAIN DICLOFENAC SODIUM TOPICAL GEL, 1% (NSAID) 100% MONEY-BACK GUARANTEE NET WT. 1.76 OZ (50g) ARTHRITIS PAIN RELIEVER



Principal Display Panel 2

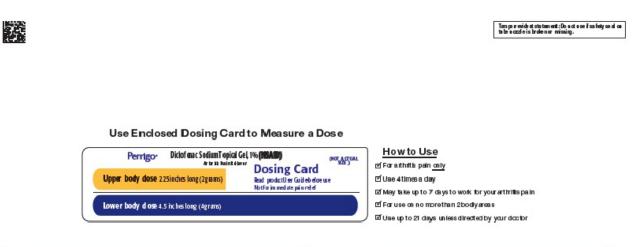
Compare to the active ingredient in Voltaren[®] Arthritis Pain berkley jensen_® ORIGINAL PRESCRIPTION STRENGTH FOR EXTERNAL USE ONLY FOR DAILY TREATMENT OF ARTHRITIS PAIN ANTI-INFLAMMATORY ARTHRITIS PAIN DICLOFENAC SODIUM TOPICAL GEL, 1% (NSAID) 100% MONEY-BACK GUARANTEE NET WT. 5.29 OZ (150g) ARTHRITIS PAIN RELIEVER



Principal Display Panel 3

Compare to the active ingredient in Voltaren[®] Arthritis Pain berkley jensen_® 3 PACK **ARTHRITIS PAIN** DICLOFENAC SODIUM TOPICAL GEL, 1% (NSAID) **ARTHRITIS PAIN RELIEVER** ORIGINAL PRESCRIPTION STRENGTH FOR DAILY TREATMENT OF ARTHRITIS PAIN ANTI-INFLAMMATORY FOR EXTERNAL USE ONLY MEDICATED GEL CLINICALLY PROVEN TO RELIEVE ARTHTRITIS PAIN **TREATMENT AREAS** HAND WRIST ELBOW FOOT ANKLE KNEE NOT FOR USE ON ANY OTHER BODY AREA (SUCH AS BACK, HIP, OR SHOULDER) THREE TUBES ONE 1.76 OZ (50g) TUBE AND TWO 5.29 OZ (150g) TUBES TOTAL NET WT 12.35 OZ (350g) **100% MONEY-BACK GUARANTEE**





Drug Facts	Dr ug Facts (comin usd)			
Active ingredient Parpae Diction acco dur (NSAD) 1%, inguina lest 1:00 2% di ction ac)	■ avoid contactwibe yes, nose,orm. outh ■ if eye contactoccurs, miseth oroughly with water Stop use and cask a dootor if			
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The risk is high or Fysu use more than drive do for for any er than directed. Denot use af you be work had and bragic medicine to any other pain of liver or to a force medican af you be work had and bragic medicine to any other pain of liver or to a force medican af you be drave and for the startar gory work be drave and for the startar gory work medicant and the same time as in the eyes, more or mouth	Read the end one <u>dUmer fails</u> to ream plete is statustores: use origot a created i will contact so more than a factor for far inparthan a directed an apply only to chean, dy with blad ose not have an you be, open wounds, his chans arash es do mort apply in some ore as any sobol product a do mort apply with external heat such as heating pad i with an topic and age over fhe these bid area. as are FANL G3D DOSNS GARDWOHH you GA bidhan actional im Topical 6(4). Hy product. The doing card is re-usable.			
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Ask ad one ror plasm so it before use if you are	Questions or comments? + 100-134-1204			
nun der a doctor'scar efor any seriou scon dii on 🛛 taking an yothe rd ng 🕨 🕨	This production otma nufactured or distributed by the owner of the registered trademark Voltarence.			



BERKLEY AND JENSEN ARTHRITIS PAIN

diclofenac sodium kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68391-205

# Item Code	Pa	ckage Description		ing Start		ting End	
NDC. C0201 205				ate	D	ate	
00	Product	GE; Type 0: Not a Combination	11/10/2021				
Quantity of Pa	arts						
Part #	art # Package Quantity			Total Product Quantity			
			50 g				
Part 2 2 TUBE		300 g					
Part 1 of 2							
BERKLEY A	ND JENS	EN ARTHRITIS PA	IN				
diclofenac sodiu	m gel						
Product Infor	mation						
tem Code (Soui	rce)	NDC:68391-871					
Route of Admini	stration	TOPICAL					
DICLOFENAC SOD	_	edient Name 6126297Q) (DICLOFENAC - UNII	:14408QL0L1)	Basis of S	_	Strengt	
nactive Ingre	dients						
		Ingredient Name				Streng	
CARBOMER HOMO		Ingredient Name PE C (ALLYL PENTAERYTHRI	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO AQ93RCW27E) COCO-CAPRYLATE	POLYMER TY	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE SOPROPYL ALCOI	POLYMER TY CAPRATE (UI HOL (UNII: ND2	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE ISOPROPYL ALCOI MINERAL OIL (UNII)	POLYMER TY E/CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP)	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE ISOPROPYL ALCOI MINERAL OIL (UNII: POLYOXYL 20 CET	POLYMER TY CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP)	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302) FHER (UNII: YRC528SWUY)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE SOPROPYL ALCOI MINERAL OIL (UNII: POLYOXYL 20 CET PROPYLENE GLYC	POLYMER TY E/CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP) FOSTEARYL E OL (UNII: 6DC9	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302) FHER (UNII: YRC528SWUY)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE SOPROPYL ALCOI MINERAL OIL (UNII: POLYOXYL 20 CET PROPYLENE GLYC WATER (UNII: 059Q	PPOLYMER TY CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP) COSTEARYL E OL (UNII: 6DC9 PF0K00R)	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302) FHER (UNII: YRC528SWUY)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE ISOPROPYL ALCOI MINERAL OIL (UNII: POLYOXYL 20 CET PROPYLENE GLYC WATER (UNII: 059Q	PPOLYMER TY CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP) COSTEARYL E OL (UNII: 6DC9 PF0K00R)	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302) FHER (UNII: YRC528SWUY)	TOL CROSSLI	NKED) (UNII:		Streng	
CARBOMER HOMO 4Q93RCW27E) COCO-CAPRYLATE ISOPROPYL ALCOI MINERAL OIL (UNII: POLYOXYL 20 CET PROPYLENE GLYC WATER (UNII: 059Q AMMONIA (UNII: 51	PPOLYMER TY CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP) COSTEARYL E OL (UNII: 6DC9 PF0K00R)	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302) FHER (UNII: YRC528SWUY)	TOL CROSSLI	NKED) (UNII:		Streng	
4Q93RCW27E) COCO-CAPRYLATE ISOPROPYL ALCOI MINERAL OIL (UNII:	PPOLYMER TY E/CAPRATE (UI HOL (UNII: ND2 : T5L8T28FGP) FOSTEARYL E OL (UNII: 6DC9 FOKOOR) .38Q19F1X)	PE C (ALLYL PENTAERYTHRI NII: 8D9H4QU99H) M416302) FHER (UNII: YRC528SWUY)		NKED) (UNII:	Marke	Streng	

	50 g in 1 TUB	E; Type 0: Not a Combination			
1	Product	, Type 0. Not a combination			
Markating	nformat	ion			
Marketing Marketing		ion tion Number or Monograpi	Marketing S	Start Marketing End	
Category	Арріса	Citation	Date	Date	
ANDA	ANDA21125	3	11/10/2021		
Part 2 of 2					
			•		
diclofenac sodiu	-	EN ARTHRITIS PAIR	4		
	iliyei				
Product Infor	mation				
ltem Code (Sour	ce)	NDC:68391-871			
Route of Admini	stration	TOPICAL			
A		NA - 1 - 4			
Active Ingredi			Pacia	of Strongth Strongth	
DICLOFENAC SOD	-	edient Name 126297Q) (DICLOFENAC - UNII:14		of Strength Strength ENAC SODIUM 10 mg in 1 g	
Incetive Incere	dianta				
Inactive Ingre	ulents	Ingredient Name		Strength	
CARBOMER HOMO 4Q93RCW27E)	POLYMER TY	PE C (ALLYL PENTAERYTHRITC	L CROSSLINKED) (
COCO-CAPRYLATE	CAPRATE (UN	III: 8D9H4QU99H)			
ISOPROPYL ALCOH		M416302)			
MINERAL OIL (UNII: POLYOXYL 20 CET		HER (UNII: YRC528SWUY)			
PROPYLENE GLYC					
WATER (UNII: 059QF0KO0R)					
AMMONIA (UNII: 51	38Q19F1X)				
Packaging					
# Item Code	Pa	ckage Description	Marketing St Date	art Marketing End Date	
1 NDC:68391-871- 00	2 in 1 CARTON				
	150 g in 1 TUE	BE; Type 0: Not a Combination			
03	Product				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA211253	11/10/2021				
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA211253	11/10/2021				

Labeler - BJWC (159082692)

Revised: 7/2023

BJWC