

DICLOFENAC SODIUM- diclofenac sodium gel
Padagis Israel Pharmaceuticals Ltd

Perrigo Diclofenac Sodium Topical Gel, 1% (NSAID) 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 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

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 us 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
<p>For your arthritis pain:</p> <ul style="list-style-type: none"> • Use 4 times per day every day • Do not use on more than 2 body areas at the same time 	<p>Use ENCLOSED DOSING CARD to measure a dose</p> <ul style="list-style-type: none"> • 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 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%

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?

1-800-719-9260

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

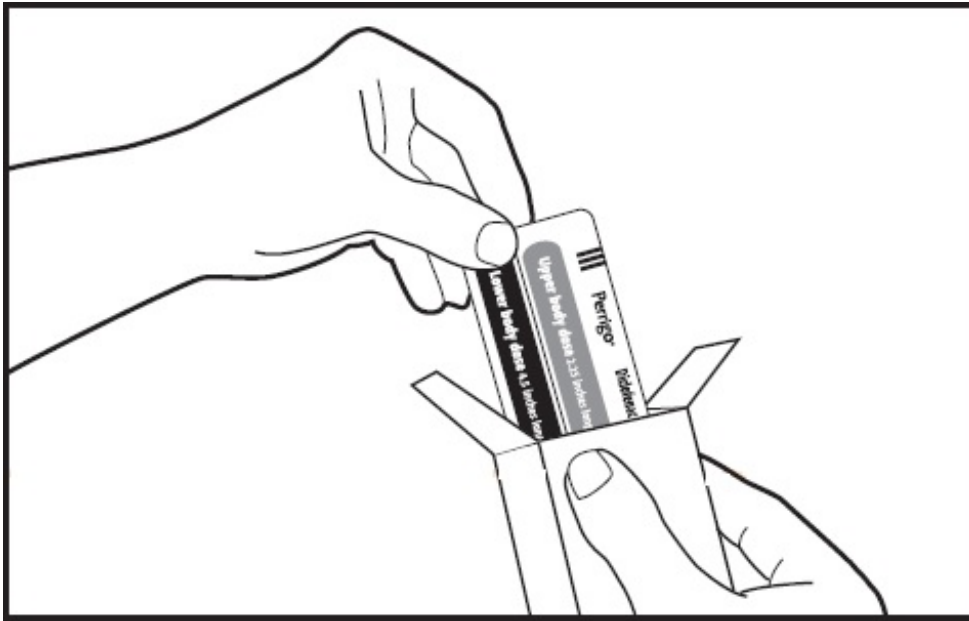
Topical Gel, 1%

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.

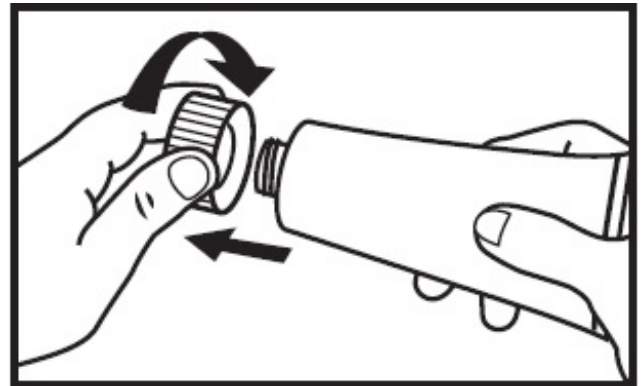
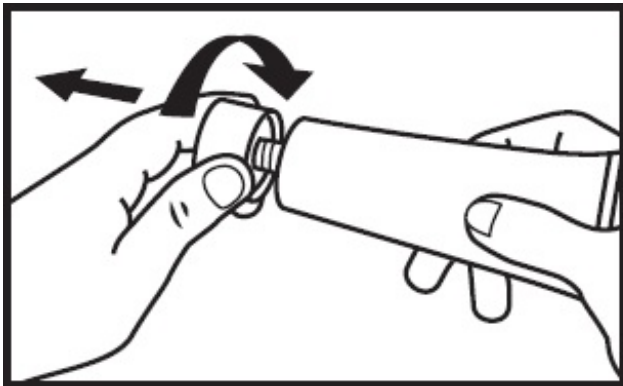


Remove the dosing card from the inside of the carton.

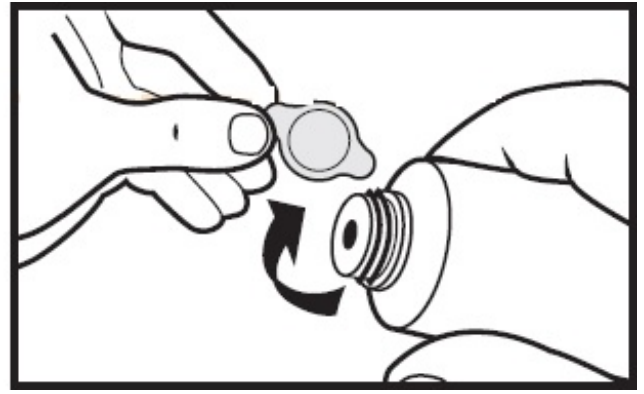
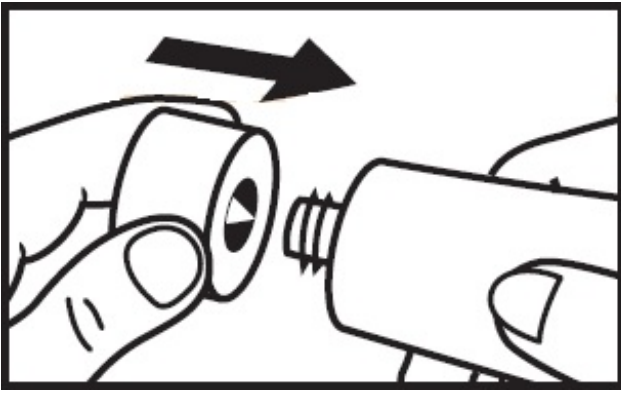
You should always use the dosing card to measure out the correct dose of Diclofenac Sodium Topical Gel, 1%.

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

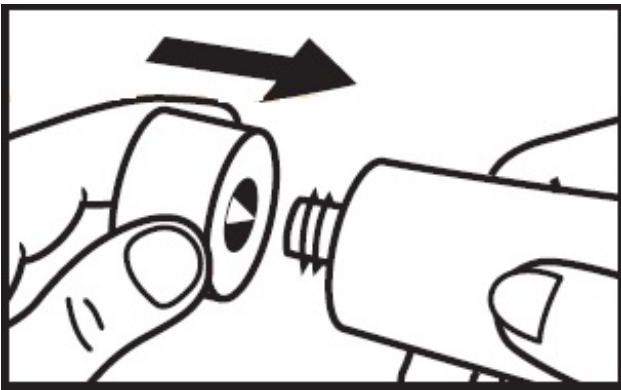
You will have either one of the tube caps shown below



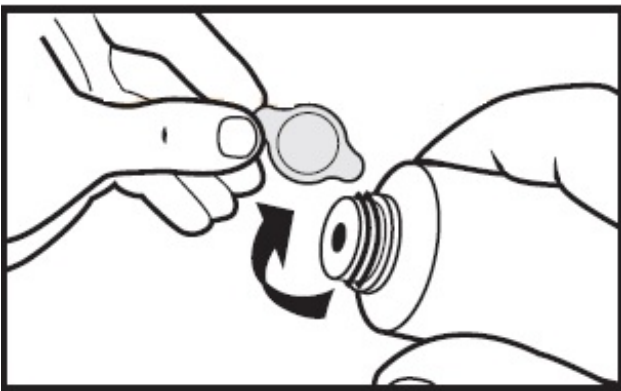
1. Take the cap off the tube.



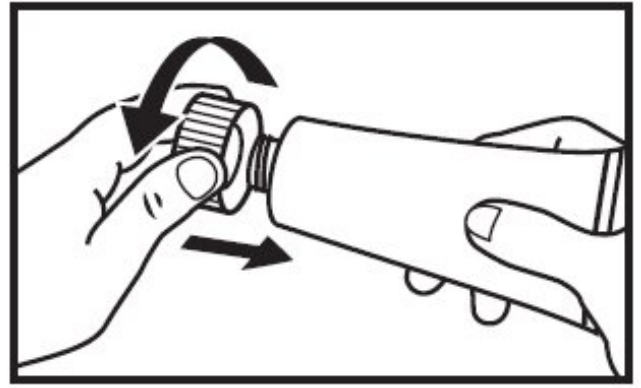
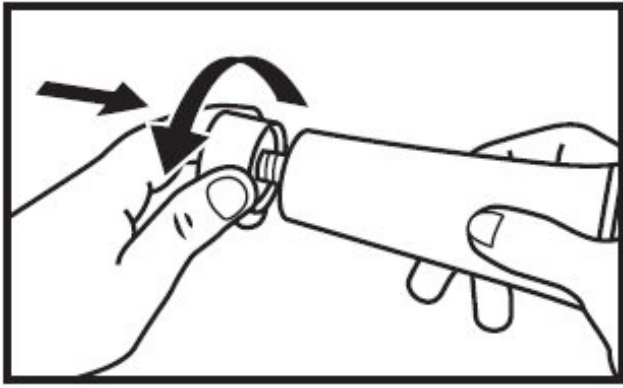
2. Open the safety seal by firmly pressing the point on the top of the cap onto the seal on the tube. Do not open the safety seal with scissors or other sharp objects.



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

How often to use Diclofenac Sodium Topical Gel, 1%

Use 4 times a day for best results.



Start of the day



Middle of the day



Late afternoon



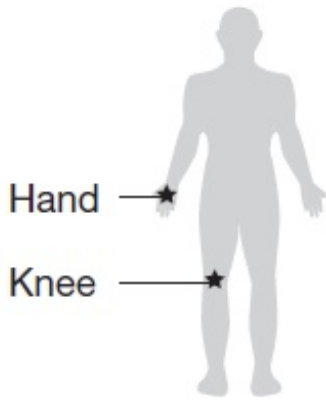
End of the day

For example:

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.

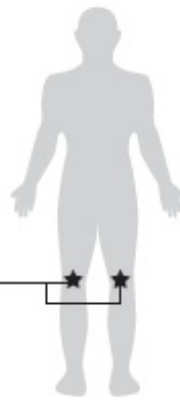
Some examples include:



Hand

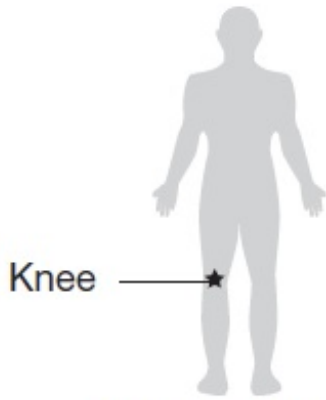
Knee

✓ Correct: 2 areas



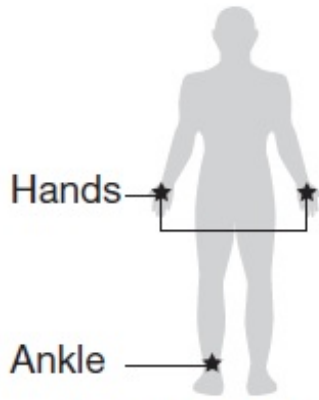
Knees

✓ Correct: 2 areas



Knee

✓ Correct: 1 area

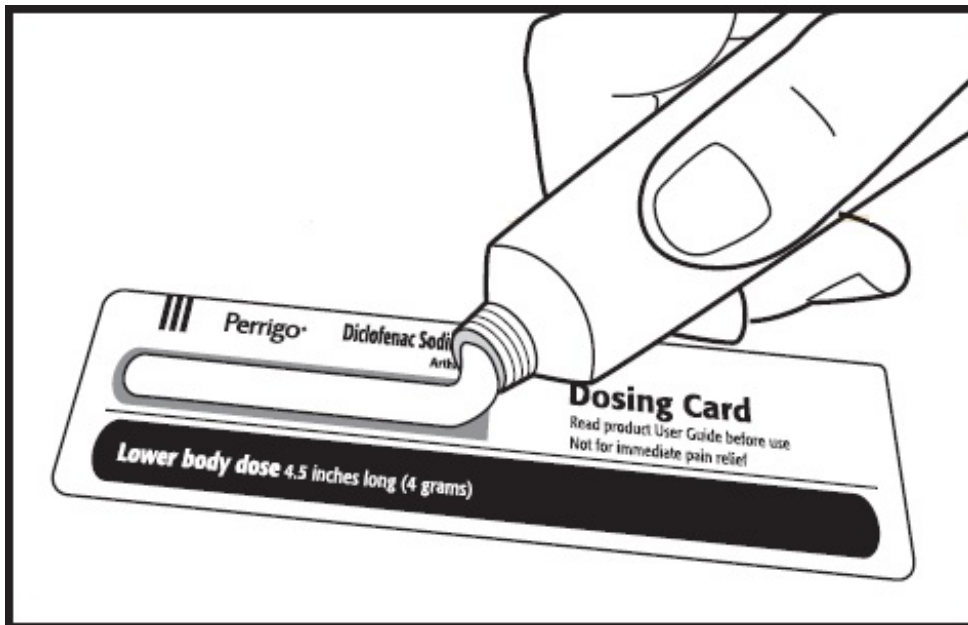


Hands

Ankle

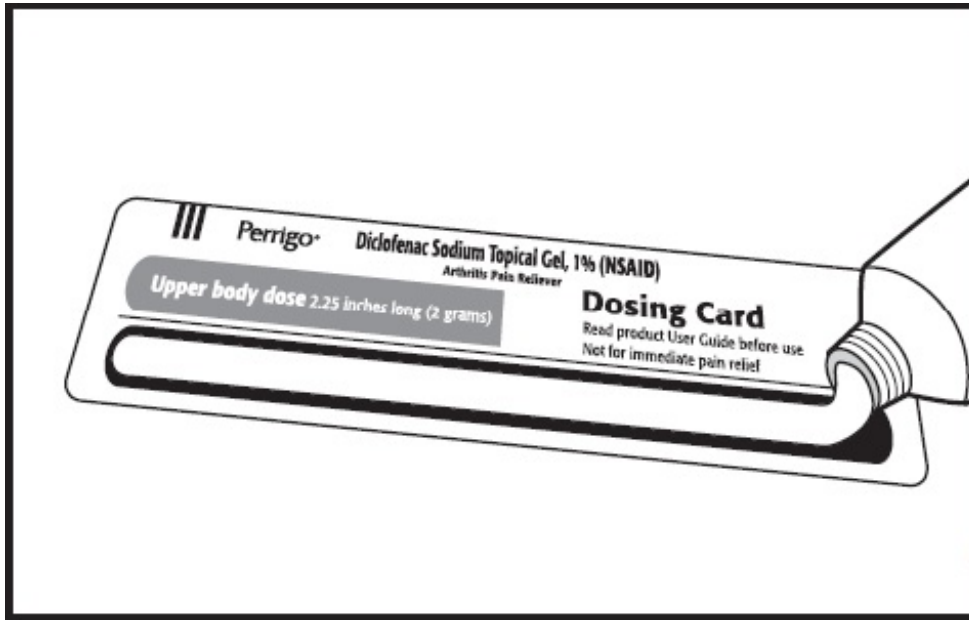
X Incorrect: 3 areas

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 1-800-719-9260 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

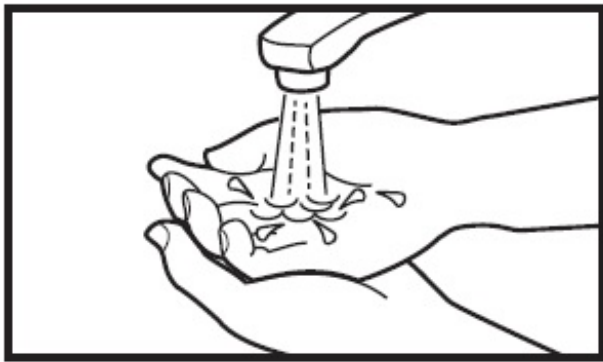
Including sides, front, and back



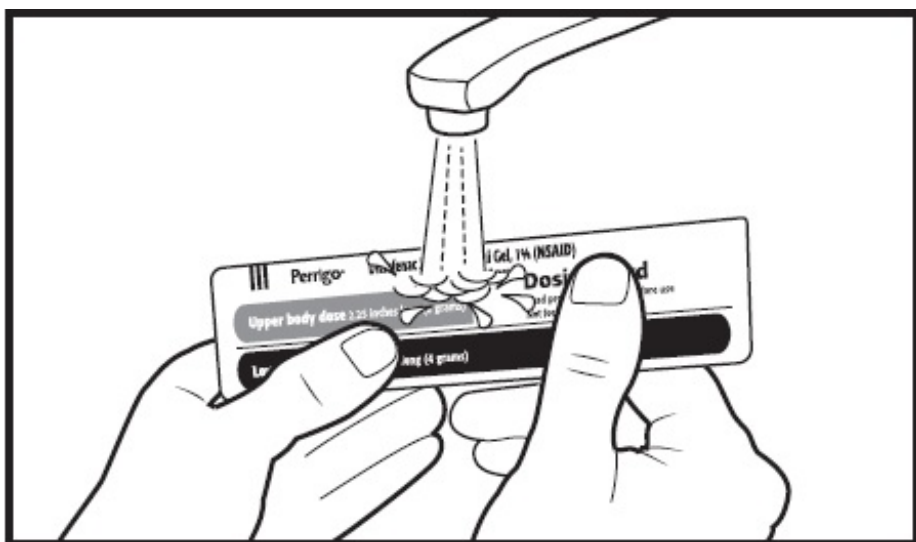
Foot

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

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

Turn over for more information

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 of 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?

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.

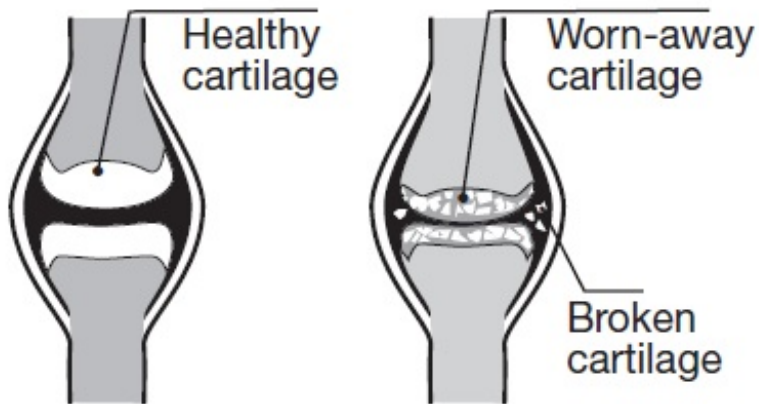
How quickly will Diclofenac Sodium Topical Gel, 1% work for arthritis pain?

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.

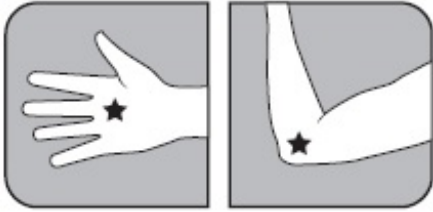
Apply Diclofenac Sodium Topical Gel, 1% 4 times a day to ensure you get the full effect of the medicine.

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:



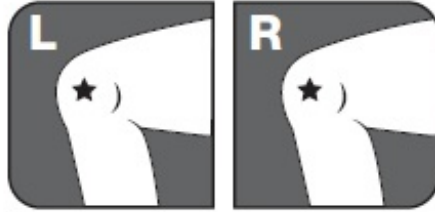
Upper body
Hand and elbow



Lower body
Knees and ankle



Upper/Lower body
Wrist 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

Padagis™

Allegan, MI 49010

www.padagis.com

87A4K RT J1

Package/Label Principal Display Panel

Compare to Voltaren® Arthritis Pain active ingredient

Diclofenac Sodium Topical Gel, 1%

(NSAID)

Arthritis Pain Reliever

For external use only

- Original Prescription Strength
- Anti-Inflammatory

- For Daily Treatment of Arthritis Pain

NET WT 3.53 OZ (100 g)

Padagis™

TREATMENT AREAS

Medicated Gel
Clinically
Proven to
Relieve Arthritis
Pain



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

NDC 45802-953-01

Compare to Voltaren® Arthritis Pain
active ingredient

Diclofenac Sodium Topical Gel, 1% (NSAID)

Arthritis Pain Reliever
For external use only

- Original Prescription Strength
- Anti-Inflammatory
- For Daily Treatment of Arthritis Pain

NET WT 3.53 OZ (100 g)



Temper-avoid statement: Do not use if safety seal on tube nozzle is broken or missing.

Made in Israel
Distributed By

Padagis™
Arlon, MI 48010
www.padagis.com



3 45802-953-01 8
87A4K RT C2

Use Enclosed Dosing Card to Measure a Dose

How to Use

Perrigo® Diclofenac Sodium Topical Gel, 1% (NSAID)
Arthritis Pain Reliever (NOT ACTUAL SIZE)

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

Upper body dose 2.25 inches long (2 grams)

Lower body dose 4.5 inches long (4 grams)

- 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

<p>Drug Facts</p> <p>Active Ingredient Diclofenac sodium 1% (NSAID) (equivalent to 0.05% diclofenac) Arthritis pain reliever (nonsteroidal anti-inflammatory drug)</p> <p>Purpose Arthritis pain reliever</p> <p>Uses For the temporary relief of arthritis pain (OAT) in the following areas: <ul style="list-style-type: none"> Hand, wrist & lower upper body areas Foot and ankle (lower body areas) The product may take up to 7 days to work for arthritis pain. It is not for immediate relief of inflammation in 7 days after use.</p> <p>Warnings For external use only. Allergy alert: Diclofenac may cause severe allergic reactions, especially in people allergic to aspirin. See your doctor if you have: asthma, asthma (wheezing), skin rashes or hives, stomach bleeding, stomach ulcers, or a long history of stomach ulcers, ulcers, or bleeding in the stomach.</p>	<p>Drug Facts (continued)</p> <p>Use with care. This product contains diclofenac. Like other NSAIDs, it may cause stomach bleeding or ulcers. Use with care if you have a history of stomach bleeding or ulcers. Do not use if you have a history of stomach bleeding or ulcers. Do not use if you have a history of stomach bleeding or ulcers. Do not use if you have a history of stomach bleeding or ulcers.</p> <p>Do not use if you have ever had a severe allergic reaction to any other pain reliever or to aspirin or NSAIDs. For more information, see the product information leaflet or ask your doctor.</p>
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Lift Flap for Important Directions & Warnings

LIFT HERE

<p>Drug Facts (continued)</p> <p>Do not use if you have ever had a severe allergic reaction to any other pain reliever or to aspirin or NSAIDs. For more information, see the product information leaflet or ask your doctor.</p> <p>Do not use if you have ever had a severe allergic reaction to any other pain reliever or to aspirin or NSAIDs. For more information, see the product information leaflet or ask your doctor.</p>	<p>Drug Facts (continued)</p> <p>Do not use if you have ever had a severe allergic reaction to any other pain reliever or to aspirin or NSAIDs. For more information, see the product information leaflet or ask your doctor.</p> <p>Do not use if you have ever had a severe allergic reaction to any other pain reliever or to aspirin or NSAIDs. For more information, see the product information leaflet or ask your doctor.</p>
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DICLOFENAC SODIUM
diclofenac sodium gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-953
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
AMMONIA (UNII: 5138Q19F1X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-953-01	1 in 1 CARTON	07/09/2020	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211253	07/09/2020	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)