

**DICLOFENAC SODIUM- diclofenac gel**  
**Scholl's Wellness Company**

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**Drug Facts**

**Active ingredient(s)**

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

\*nonsteroidal anti-inflammatory drug

**Purpose**

Arthritis pain reliever

**Use(s)**

for the temporary relief of arthritis pain ONLY in the following areas

head, 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 the age of 18 years. It is not known if this drug works or is safe in children under the age of 18 years.

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

- 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 of side of body
- slurred speech

## Pregnancy/Breastfeeding

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

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.

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### Daily

#### For your arthritis pain:

Use 4 times per day every day  
Do not use on more than 2 body areas at the same time

### Per Dose

#### 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)

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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 areas as any other product
- do not apply with external heat such as a 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**

☐ read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.

### **Storage**

☐ store at 20° to 25° C (68° to 77° F). Keep from freezing.

### **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?**

Call 1-866-360-3226 (Monday through Friday 9AM - 5PM EST)

Distributed by:

**Scholl's® Wellness Company LLC**

Parsippany, NJ 07054

Rev. 10-2020-00

### **ARTHRITIS PAIN RELIEVER**

**Diclofenac sodium topical gel, 1% (NSAID) - arthritis pain reliever  
User Guide**

## **How to use Dr. Scholl's® Arthritis Pain Reliever, with answers to frequently asked questions**

### **Quick Start**

#### **How to get started right away with Dr. Scholl's® Arthritis Pain Reliever**

#### **Understanding Dr. Scholl's® Arthritis Pain Reliever**

Dr. Scholl's® Arthritis Pain Reliever (diclofenac sodium topical gel, 1% (**NSAID**) - arthritis pain reliever) is an arthritis pain relief medication that you apply to your skin.

#### **Before You Use Dr. Scholl's® Arthritis Pain Reliever**

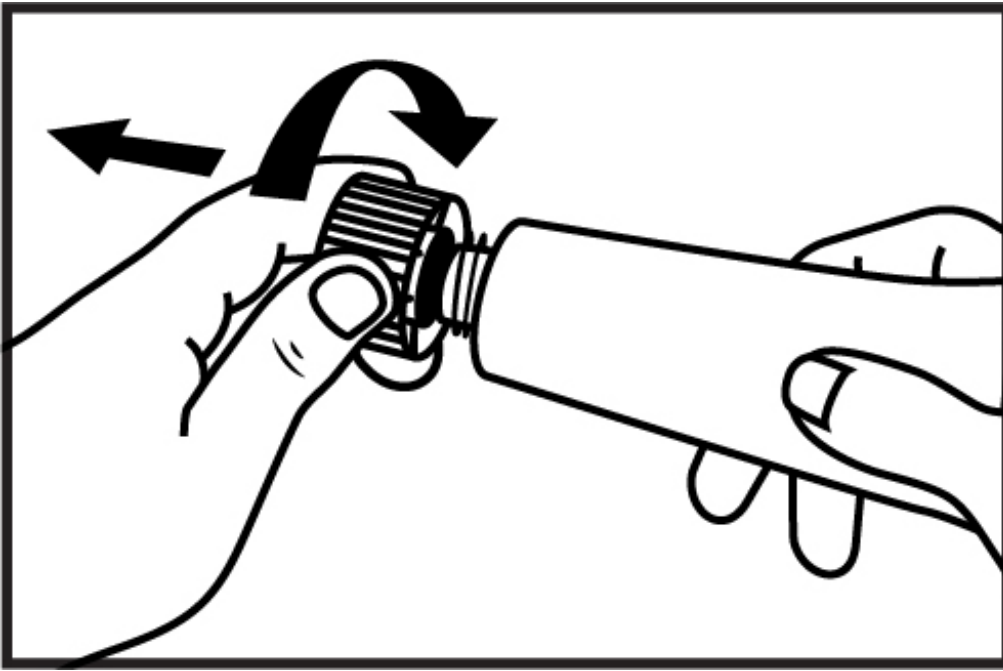
Read the Drug Facts Label, which appears on the carton.



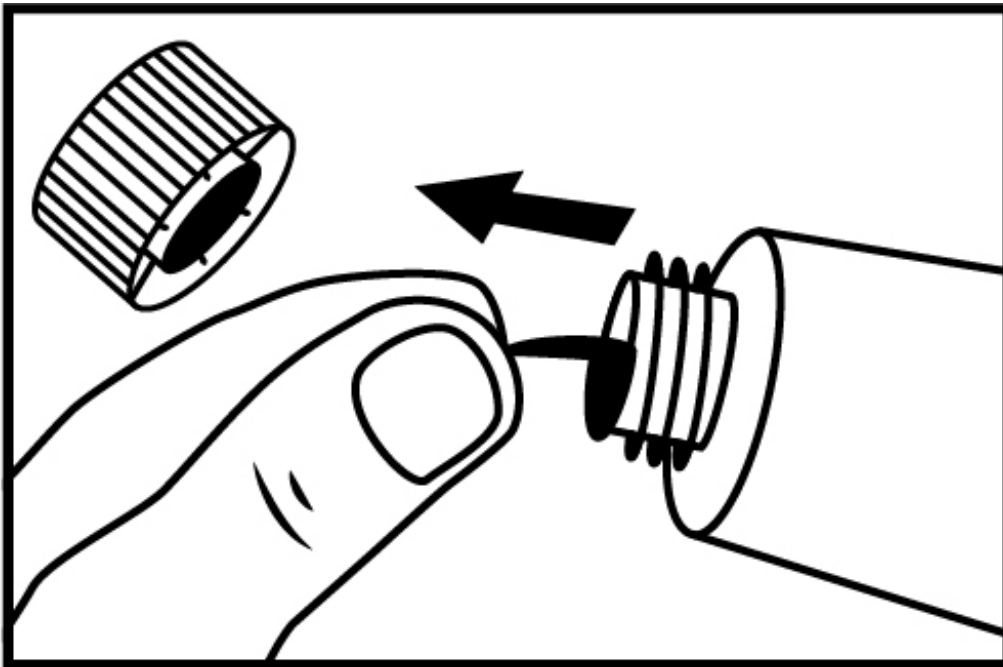
Remove the dosing card from the inside of the carton. You should always use the dosing card to measure out the correct dose of Dr. Scholl's® Arthritis Pain Reliever.

#### **The first time you use a tube of Dr. Scholl's® Arthritis Pain Reliever:**

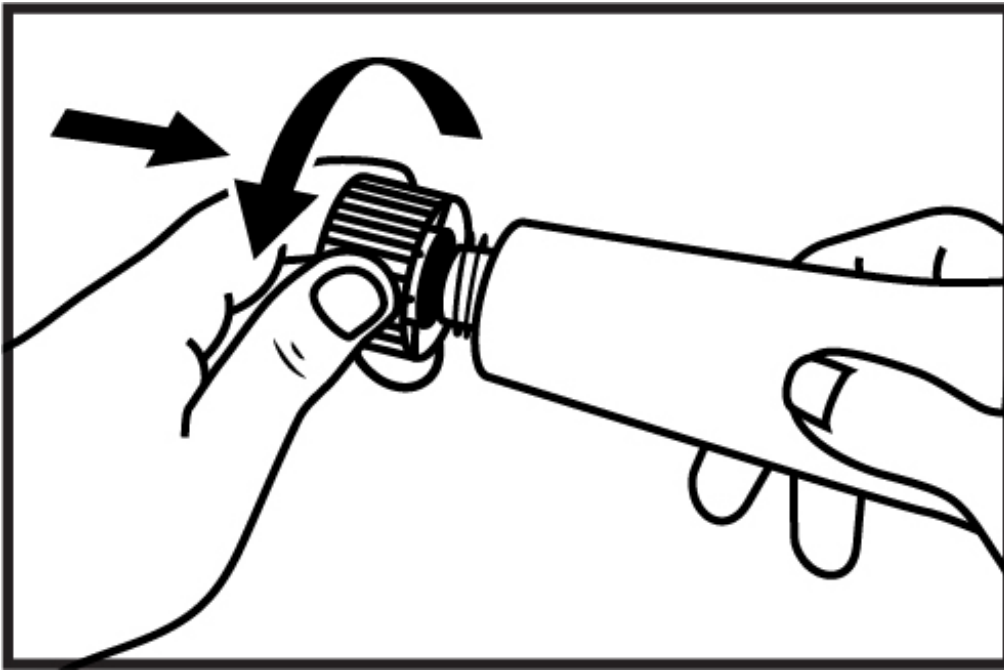
1. Take the cap off the tube.



2. Lift tab and pull to remove foil seal prior to use. Do not open the safety seal with the scissors or other sharp objects.



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



### **Using Dr. Scholl's® Arthritis Pain Reliever**

#### **How often to use Dr. Scholl's® Arthritis Pain Reliever**

Use 4 times a day for best results.

For example:



Start of the day



Middle of the day



Late afternoon

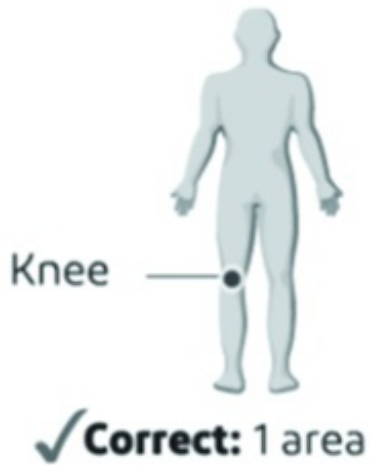


End of the day

#### **Where to apply Dr. Scholl's® Arthritis Pain Reliever**

Dr. Scholl's® Arthritis Pain Reliever can be used on up to 2 body areas from the following list: a foot, an ankle, a knee, a hand, a wrist, an elbow. 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).

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**Lost Your Dosing Card? Don't worry!  
Call 1-866-360-3226 to get a free replacement.**

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### **Applying Dr. Scholl's® Arthritis Pain Reliever**

Gently rub Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever**



**Wash your hands** after applying Dr. Scholl's® Arthritis Pain Reliever. 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 Dr. Scholl's® Arthritis Pain Reliever 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 tanning booths)
- use in the 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 Dr. Scholl's® Arthritis Pain Reliever**

**Do not use Dr. Scholl's® Arthritis Pain Reliever...**

- 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 is...**

- you have problems or 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

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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.

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

##### **Allergy alert**

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

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

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 thinner (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 Dr. Scholl's® Arthritis Pain Reliever...**

- 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 any 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 Dr. Scholl's® Arthritis Pain Reliever. The dosing card is re-usable.

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

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

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Stop using Dr. Scholl's® Arthritis Pain Reliever 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

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- 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 Dr. Scholl's® Arthritis Pain Reliever**

#### **Can I use Dr. Scholl's® Arthritis Pain Reliever 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.

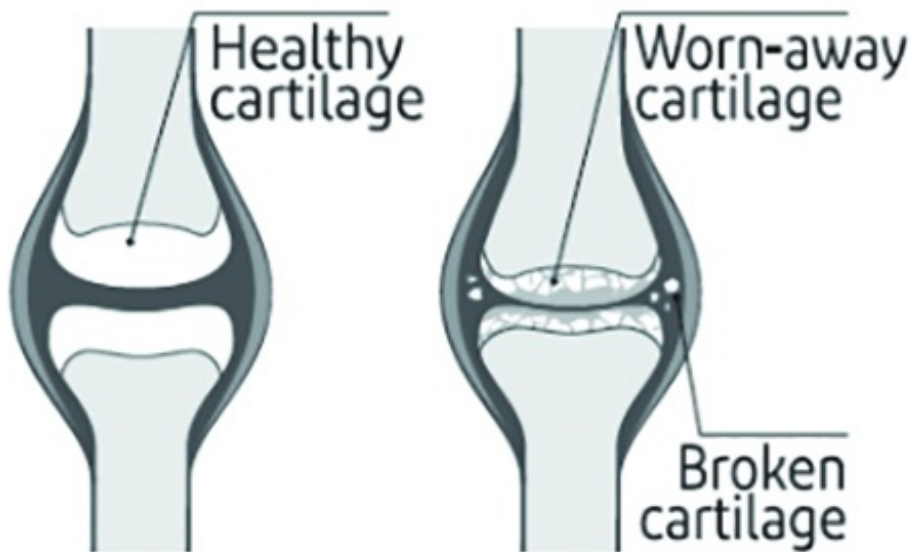
#### **How quickly will Dr. Scholl's® Arthritis Pain Reliever work for arthritis pain?**

Diclofenac sodium topical gel 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 Dr. Scholl's® Arthritis Pain Reliever used for?**

Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever work?**

Diclofenac sodium, the medicine in Dr. Scholl's® Arthritis Pain Reliever, is a nonsteroidal anti-inflammatory drug (NSAID). NSAIDs are used to treat pain from medical conditions such as arthritis. Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever differ from prescription diclofenac sodium topical gel?**

Over-the-counter Dr. Scholl's® Arthritis Pain Reliever is the same strength and formula as original full prescription strength diclofenac sodium topical gel but is available without a prescription.

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Apply Dr. Scholl's® Arthritis Pain Reliever 4 times a day to ensure you get the full effect of the medicine.

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### **Can I apply Dr. Scholl's® Arthritis Pain Reliever to upper and lower body areas at the same time?**

**Yes.**

You can use Dr. Scholl's® Arthritis Pain Reliever on up to 2 body areas at the same time. The areas can include 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 Dr. Scholl's® Arthritis Pain Reliever on more than 2 body areas at once.*

**Can I apply Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever on my spine, hips, or shoulders?**

**No.**

The use of Dr. Scholl's® Arthritis Pain Reliever on the spine, hips, and shoulders has not been studied.

**Can I take any other pain medications with Dr. Scholl's® Arthritis Pain Reliever?**

Ask your doctor or pharmacist before using Dr. Scholl's® Arthritis Pain Reliever if you are already 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 Dr. Scholl's® Arthritis Pain Reliever?**

Taking other pain medications is generally not recommended. Speak with your doctor or pharmacist before taking other pain medications when using Dr. Scholl's® Arthritis Pain Reliever.

**How long can I use Dr. Scholl's® Arthritis Pain Reliever?**

Use Dr. Scholl's® Arthritis Pain Reliever 4 times a day every day for up to 21 days for treatment of arthritis pain or as directed by your doctor.

Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever into a complete program to help manage your arthritis pain.

**What do I do if I get Dr. Scholl's® Arthritis Pain Reliever 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 Dr. Scholl's® Arthritis Pain Reliever?**

If you forget to apply Dr. Scholl's® Arthritis Pain Reliever, don't double your dose. Just apply the next dose as scheduled.

**How should I store Dr. Scholl's® Arthritis Pain Reliever?**

- Store at 20° to 25°C (68° to 77°F).
- Do not freeze Dr. Scholl's® Arthritis Pain Reliever.
- Store the dosing card with your Dr. Scholl's® Arthritis Pain Reliever.
- Keep out of the reach of children.

**Additional Questions?**

Call the Dr. Scholl's® Arthritis Pain Reliever consumer hotline at 1-866-360-3226.  
[www.drscholls.com](http://www.drscholls.com)

Distributed by:

**Scholl's® Wellness Company LLC**

Parsippany, NJ 07054

Rev. 10-2020-00

**Principal Display Panel**

Dr.Scholl's

# ARTHRITIS PAIN RELIEVER

diclofenac sodium topical gel, 1% (NSAID)  
arthritis pain reliever

**NEW**

NDC 73469-2053-8

Same active ingredient as prescription strength Voltaren® Arthritis Pain\*\*

Dr.Scholl's

# ARTHRITIS PAIN RELIEVER

diclofenac sodium topical gel, 1% (NSAID)  
arthritis pain reliever

FOR DAILY TREATMENT OF ARTHRITIS PAIN

ANTI-INFLAMMATORY

FOR EXTERNAL USE ONLY

NET WT  
1.76 oz (50 g)

\*\*Not manufactured or distributed by Voltaren® trademark owner



## TREATMENT AREAS

Medicated Gel  
Clinically Proven  
to Relieve  
Arthritis Pain

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

889010000

### Use Enclosed Dosing Card to Measure a Dose

Dr.Scholl's

## ARTHRITIS PAIN RELIEVER

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)

**Dosing Card (Not Actual Size)**  
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
- † Tamper evident statement. Do not use if foil seal on tube opening is broken or missing.

Made in the USA with domestic and globally sourced ingredients

#### Drug Facts (continued)

- 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 areas as any other product
- do not apply a bandage over the treated area
- do not apply with external heat such as a heating pad
- store ENCLOSED DOSING CARD with your Dr. Scholl's® Arthritis Pain Reliever. The dosing card is re-usable.

#### Other information

- store at 20° to 25°C (68° 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.

#### Drug Facts (continued)

**Inactive ingredients** carboxer homopolymer Type C, cocoyl caprylocarbate, fragrance, isopropyl alcohol, mineral oil, polyvinyl 20 octadecyl ether, propylene glycol, purified water, strong ammonia solution

#### Questions or Comments?

Call 1-866-360-3226

Dr. Scholl's® is a trademark of Scholl's Wellness Company.

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Dist. by: Scholl's Wellness Company LLC

Parispany, NJ 07054



DICLOFENAC SODIUM

diclofenac gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73469-2053
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	white (white to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73469-2053-1	1 in 1 CARTON	10/30/2020	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:73469-2053-8	1 in 1 CARTON	10/30/2020	
2		50 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	ANDA208077	10/30/2020	

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**Labeler** - Scholl's Wellness Company (117174744)

**Registrant** - Amneal Pharmaceuticals of New York, LLC (123797875)

**Establishment**

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		079389286	analysis(73469-2053) , label(73469-2053) , manufacture(73469-2053) , pack(73469-2053)

Revised: 1/2023

Scholl's Wellness Company