MOTRIN ARTHRITIS PAIN- diclofenac sodium gel Johnson & Johnson Consumer Inc.

MOTRIN ARTHRITIS PAIN

Drug Facts

Active ingredient

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

*nonsteroidal anti-inammatory 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		
	Use ENCLOSED DOSING CARD to measure a		
 For your arthritis pain: 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 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 Motrin® Arthritis Pain 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, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution

Questions or comments?

Call **1-800-962-5357** (toll-free) or **215-273-8755** (collect) or visit www.motrin.com

PRINCIPAL DISPLAY PANEL

NDC 50580-574-02

Original

Prescription

Strength

New!

Different Ingredient

Diclofenac Sodium

Motrin ®

ARTHRITIS PAIN

Diclofenac Sodium

Topical Gel, 1% (NSAID)

ARTHRITIS PAIN RELIEVER

Anti-inflammatory

For daily treatment of

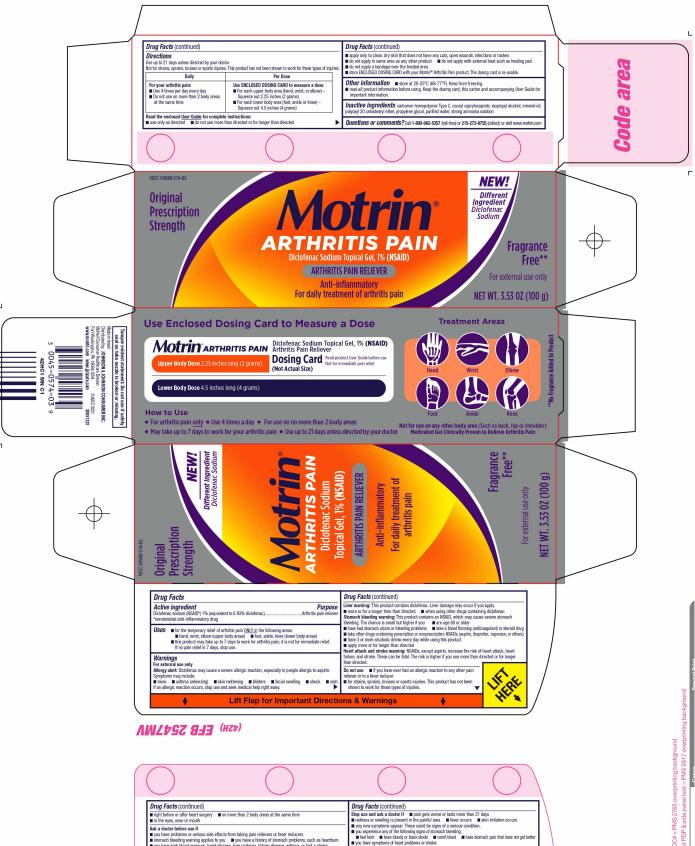
arthritis pain

Fragrance

Free**

For external use only

NET WT. 3.53 OZ (100 g)





Motrin ARTHRITIS PAIN Diclofenac Sodium Topical Gel, 1% (NSAID) Arthritis Pain Reliever

User Guide
How to use Motrin® Arthritis Pain Gel with answers to frequently asked questions

Guick Start How to get started right away with Motrin* Arthritis Pain Gel Understanding Motrin* Arthritis Pain Gel Motrin* Arthritis Pain (Dicolenae Sodium Topical Gel, 1% (NSAID) —arthritis pain rieled medication that you apply to your skin.

ore You Use Motrin* Arthritis Pain Gel d 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 Motrin® Arthritis Pain Gel.

The first time you use a tube of Motrin® Arthritis Pain Gel: You will have either one of the tube caps shown below























iring the correct amount using the dosing card













After You Use Motrin® Arthritis Pain Gel



Wash your hands after applying Motrin® Arthritis Pain Gel. If the treated area is the hands wait up to 1 hour to





- If eye contact coours, rise showughly with water Facts you need to know Morrier Arthrifs Pain Gel Do ent use Mothrif Arthrifs Pain Gel Do ent use Mothrif Arthrifs Pain Gel Law Siyo hime ever had an allege resolt on to any other pain reliever or to a fever reducer.

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Heart attack, and stroke warning

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Stop using Motrin® Arthritis Pain Gel and ask a doctor

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What is Mortin' Arthrills Pain del can be used for the store relief of arthrills pain of the store. See feel, relief of arthrills pain in the hands, which schools, feet, common form of arthrills. It mainly affects a type of tissue common form of arthrills. It thinks the joins and prevents the border from paint pain





the medicine in Motrin® Arthritis Pain Gel is absorbed in the bloodstream. It works by penetrating through your skin at the application site to deliver arthritis pain relief.

Sodium Topical Gel, 1%?

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





Upper/Lower body Wrist and ankle

Can I apply Motrin® Arthritis Pain Gel 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.

ero snoulders has not been studied.

Can I take any other pain medications with Motrin^a
Arthritis Pain Germandist before using Motrin^a
Ask your doctor or pharmacist before using Motrin^a
Arthritis Pain Gel You are taking any other pain reliever
or are planning on taking any other pain reliever
specially prescription or nonprescription NSAIDs
(aspirin, ibuprofen, naproxen, or others).

Arthritis Pain Gel.

How long can Luse Mortin's Arthritis Pain Gel?

Lee Mortin's Arthritis Pain Gel 2 Lines a day every day for by Lee Mortin's Arthritis Pain Gel 4 Lines a day every day for by your doubter.

Mortin's Arthritis Pain Gel should be pain of an overall program for managing your arthritis pain. The program should also include activities such as genoprished exhould also include activities and as genoprished weight maniferance. Regular visits and discussions with your doctor can help incorporate Mortin's Arthritis Pain Gel Into a complete program to help manage your without the company of the company of

What do I do if I get Motrin® Arthritis Pain Gel 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.

- Now should 1 store Motrin* Arthritis Pain Gel?

 Store at 20-25°C (68-77°F).

 Do not freeze Motrin* Arthritis Pain Gel.

 Store the dosing card with your Motrin* Arthritis Pain Gel.

 Keep out of reach of children.

Additional Questions?
Call 1-800-962-5357 (toll-free) or 215-273-8755 (collect) or visit www.motrin.com

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McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2021



diclofenac sodium gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50580-574

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:14408QL0L1) DICLOFENAC SODIUM 9.3 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
AMMONIA (UNII: 5138Q19F1X)		
MINERAL OIL (UNII: T5L8T28FGP)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50580-574- 01	1 in 1 CARTON	06/20/2022		
1		50 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:50580-574- 02	1 in 1 CARTON	06/20/2022		
2		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	06/20/2022	

Labeler - Johnson & Johnson Consumer Inc. (878046358)