

MOTRIN ARTHRITIS PAIN- diclofenac sodium gel
Kenvue Brands LLC

MOTRIN 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 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 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
<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 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)

Code area

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

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

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Drug Facts (continued)
 ■ apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes
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Other information
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Inactive ingredients carbomer homopolymer Type C, cetyl caprylocaprate, isopropyl alcohol, mineral oil, polyoxy 20 cetearyl ether, propylene glycol, purified water, strong ammonia solution

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NDC 50580-574-02

Original Prescription Strength

Motrin®

ARTHROSIS PAIN

Diclofenac Sodium Topical Gel, 1% (NSAID)

ARTRHOSIS PAIN RELIEVER

Anti-inflammatory
For daily treatment of arthritis pain

NEW!
Different Ingredient
Diclofenac Sodium

Fragrance Free**

For external use only

NET WT. 3.53 OZ (100 g)

Use Enclosed Dosing Card to Measure a Dose

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

Dosing Card (Not Actual Size)
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)

Treatment Areas

Hand Wrist Elbow
Foot Ankle Knee

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

Not for use on any other body area (Such as back, hip or shoulder)
Medicated Gel Clinically Proven to Relieve Arthritis Pain

**No Fragrance Added to Product

NDC 50580-574-02

Original Prescription Strength

Motrin®

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Diclofenac Sodium Topical Gel, 1% (NSAID)

ARTRHOSIS PAIN RELIEVER

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Drug Facts (continued)
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 ■ 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.
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LIFT HERE

Lift Flap for Important Directions & Warnings

(42H) EFB 2547MV

Drug Facts (continued)
 ■ right before or after heart surgery ■ on more than 2 body areas at the same time
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 ■ you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.

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 ■ 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

Drug Facts (continued)
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.

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USER GUIDE

Motrin® & NDC# = PMS 2765 overprinting background
 All dark violet PDP & side panel text = PMS 2617 overprinting background

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	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			

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 - Kenvue Brands LLC (118772437)

