VOLTAREN ARTHRITIS PAIN- diclofenac sodium gel
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GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredient

Diclofenac sodium 1% (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Arthritis pain reliever

Keep out of reach of children.

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

Uses

- for the treatment 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

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/fever reducer
- for strains, sprains, bruises or sports 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

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. 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
- 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 this product during the last 3 months of 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.

Directions

Use up to 21 days unless directed by your doctor

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)

Read the enclosed Consumer 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

Other Information

- store at 20-25°C (68-77°F). Keep from freezing.
- read all product information before using. Keep the dosing card, this box and accompanying leaflet for important information.

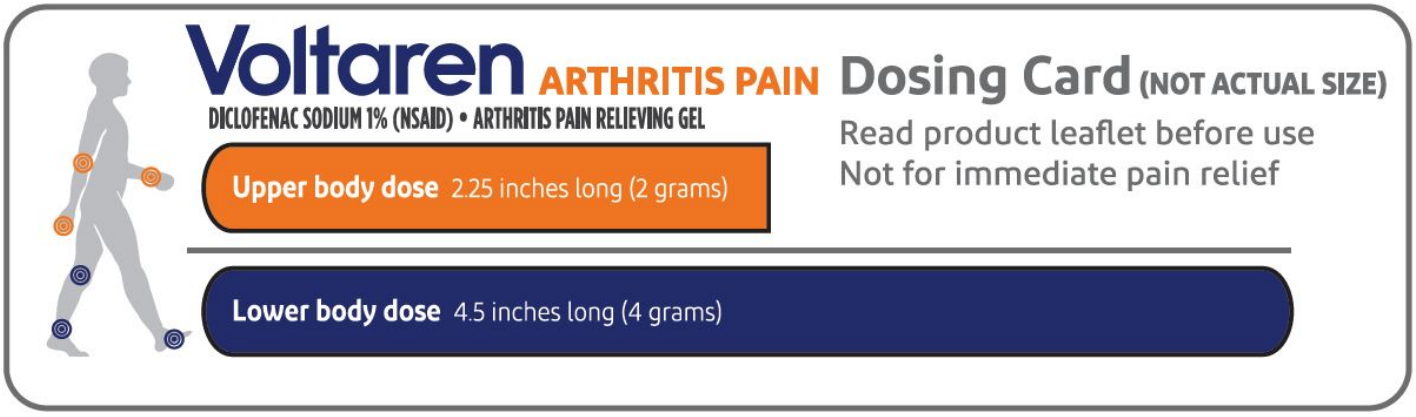
Inactive Ingredients

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?

1-855-297-3031

Use Enclosed Dosing Card to Measure a Dose



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

Principal Display Panel

NDC 0067-8152-02

Voltaren

ARTHRITIS PAIN

NEW

Diclofenac sodium 1% (NSAID) • Arthritis Pain Relieving Gel

For Daily Treatment of Arthritis Pain

Anti-Inflammatory

FULL PRESCRIPTION STRENGTH

TREATMENT AREAS

Powerful Medicated Gel

Clinically Proven to Treat Arthritis Pain

Voltaren Emulgel ™

Hand Wrist Elbow Foot Ankle Knee

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

Non Greasy Gel

Clean Scent

NET WT 1.76 oz (50 g)

Made in Canada

Distributed by: **GSK Consumer Healthcare**, Warren NJ 07059

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Principal Display Panel

NDC 0067-8153-01

Voltaren

ARTHRITIS PAIN

Diclofenac sodium 1% (NSAID) • Arthritis Pain Relieving Gel

FULL PRESCRIPTION STRENGTH

NEW

Powerful Medicated Gel

Clinically Proven to Treat Arthritis Pain

Voltaren Emulgel ™

- **For Daily Treatment of Arthritis Pain**
- **Anti-Inflammatory**
- **Non Greasy Gel**
- **Clean Scent**

TREATMENT AREAS

Hand Wrist Elbow Foot Ankle Knee

EASY TWIST CAP*

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

NET WT 2 x 150 g + 50 g (350 g)

Made in Canada

Distributed by: **GSK Consumer Healthcare**, Warren NJ 07059

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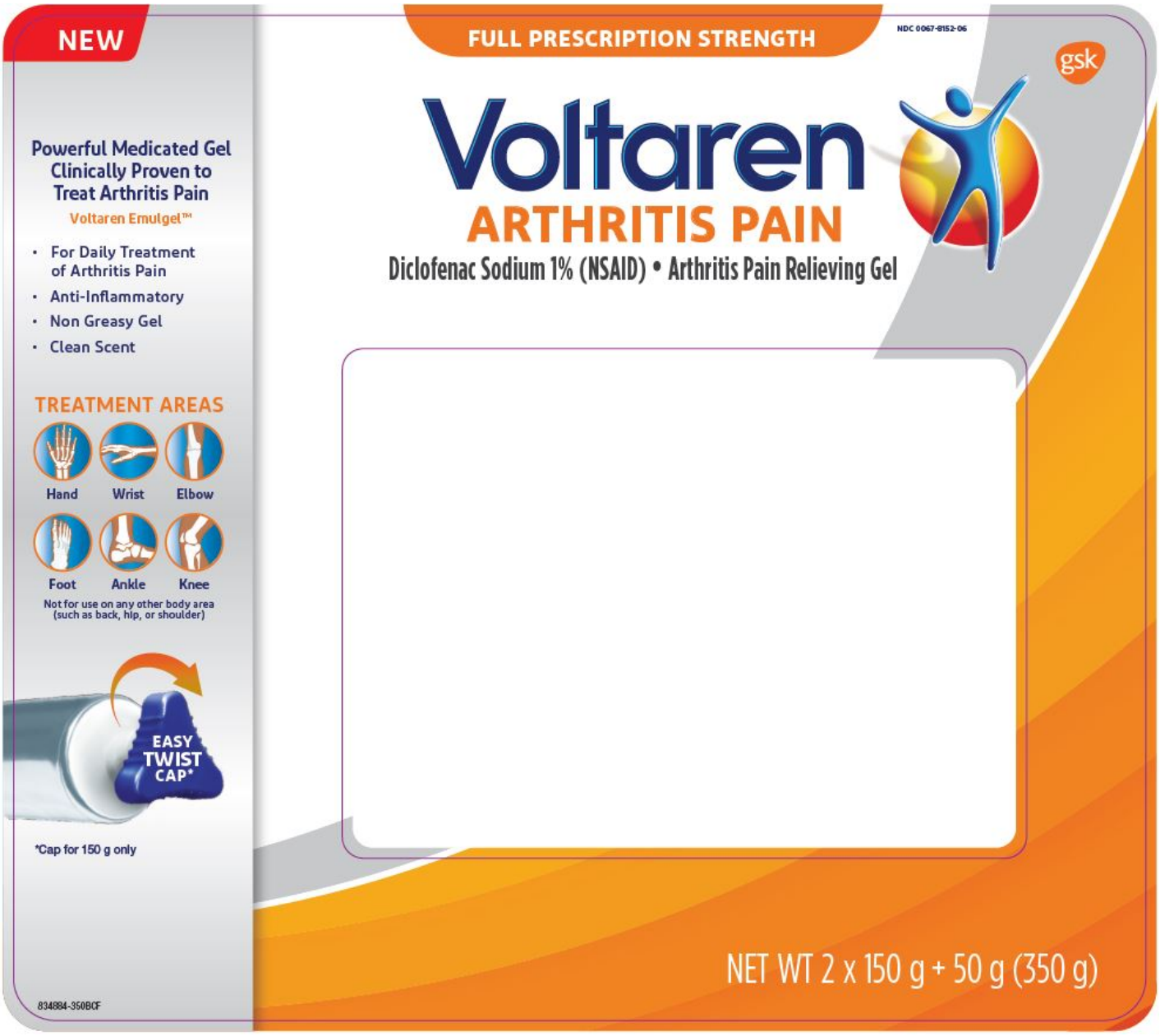

VOLTAREN ARTHRITIS PAIN

diclofenac sodium gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8152
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
AMMONIA (UNII: 5138Q19F1X)	
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: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8152-01	1 in 1 CARTON	05/13/2020	
1		20 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		
2	NDC:0067-8152-02	1 in 1 CARTON	05/13/2020	
2		50 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		
3	NDC:0067-8152-03	1 in 1 CARTON	05/13/2020	
3		100 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		
4	NDC:0067-8152-04	1 in 1 CARTON	05/13/2020	
4		150 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		
5	NDC:0067-8152-05	3 in 1 CARTON	05/13/2020	
5		150 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022122	05/13/2020	

VOLTAREN ARTHRITIS PAIN

diclofenac sodium kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8153

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8153-01	1 in 1 CARTON; Type 0: Not a Combination Product	05/13/2020	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 TUBE	300 g
Part 2	1 TUBE	50 g

Part 1 of 2

VOLTAREN ARTHRITIS PAIN

diclofenac sodium gel

Product Information	
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**
AMMONIA (UNII: 5138Q19F1X)	
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: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		2 in 1 KIT		
1		150 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
NDA authorized generic	NDA022122	03/31/2020	

Part 2 of 2

VOLTAREN ARTHRITIS PAIN

diclofenac sodium gel

Product Information

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
AMMONIA (UNII: 5138Q19F1X)	
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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1		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
NDA	NDA022122	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022122	03/31/2020	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations

Pharmanalytica SA		487967499	ANALYSIS(0067-8152, 0067-8153)

Revised: 2/2020 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC