



GSK Regulatory Spec Box	Verified Date:
Drug Facts Info	
Drug Facts	Helvetica Bold Condensed Italic
Drug Facts (continued)	Helvetica Bold Condensed Italic / Condensed
Headings	Helvetica Bold Condensed Italic
Subheadings	Helvetica Bold Condensed
Body text	Helvetica Condensed / Bold Condensed
Bullets	Helvetica Condensed
Dashes on same line and of statement separated from "Drug Facts" statement by two lines	
Spacing of the bar lines from edge of box is a minimum of 2 spaces either side of Drug Facts Box	
Tracking:	Horizontal Scale:
Leading:	Maximum Characters/Inch:
Bullseye:	Half-Inch:
Size of Net Wt/Contents (Smallest character height in inches)	
PDP dimensions (in square inches)	
Ratio of Statement of Identity to Logo/Largest Copy on PDP	
Statement of Identity (in Condensed) to Largest Logo Copy (in)	
Vertical PDP:	Horizontal PDP:



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Bullets	Helvetica Condensed
Dashes on same line and of statement separated from "Bullet" statement by two ems	
Spacing of the bar lines from edge of line is a minimum of 2 spaces either side of Drug Fact Box	
Tracking:	Horizontal Scale:
Leading:	Maximum Characters/Inch:
Bullseye:	Half/Inch:
Size of Net Wt/Contents (Smallest character height in inches)	
PDP dimensions (in square inches)	
Ratio of Statement of Identity to Logo/Largest Copy on PDP	
Statement of Identity (S) (Divided by Largest Logo Copy (L))	
Vertical PDP:	Horizontal PDP:

Voltaren

ARTHRITIS PAIN

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

NPA008448

NPA008448


User Guide

How to use Voltaren Arthritis Pain, with answers to frequently asked questions

Quick Start
How to get started right away with Voltaren Arthritis Pain


Understanding Voltaren Arthritis Pain Gel
Voltaren Arthritis Pain (diclofenac sodium topical gel, 1% (NSAID) - arthritis pain reliever) is an arthritis pain relief medication that you apply to your skin. It is intended to be used 4 times a day every day for up to 21 days.

Before You Use Voltaren Arthritis Pain
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 Voltaren Arthritis Pain.

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




indent




indent

1. Take the cap off the tube. Open the safety seal by firmly pressing the indent on the top of the cap onto the star-shaped seal on the tube.
2. Firmly turn the cap to remove the safety 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 Voltaren Arthritis Pain
How often to use Voltaren Arthritis Pain
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 Voltaren Arthritis Pain
Voltaren Arthritis Pain 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:



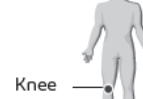
Hand

✓ Correct: 2 areas



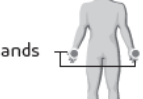
Knees

✓ Correct: 2 areas



Knee


✓ Correct: 1 area



Hands

✗ 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).

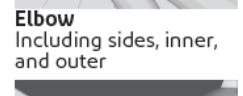
For each lower body area (a foot, an ankle, or a knee): Squeeze gel from the tube equal to the length shown on the lower body section of the dosing card (4.5 inches).

Lost Your Dosing Card? Don't worry!
Call 1-855-297-3031 to get a free replacement.


Applying Voltaren Arthritis Pain
Gently rub Voltaren Arthritis Pain 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

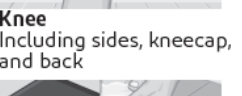


Wrist
Including sides, top, and bottom




Lower body areas

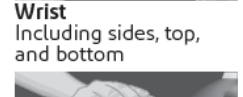
Knee
Including sides, kneecap, and back



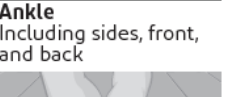
Ankle
Including sides, front, and back




Hand
Including top, palm, and fingers




Foot
Including sole, top of foot, and toes



After You Use Voltaren Arthritis Pain



Wash your hands after applying Voltaren Arthritis Pain. 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 Voltaren Arthritis Pain 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 Voltaren Arthritis Pain

Do not use Voltaren Arthritis Pain...

- 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
- 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

Turn over for more information ➡

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
- 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 thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription 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 Voltaren Arthritis Pain...

- 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 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 Voltaren Arthritis Pain. 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.

Stop using Voltaren Arthritis Pain 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


Questions and Answers
Answers to questions you may ask about Voltaren Arthritis Pain

Can I use Voltaren Arthritis Pain for the immediate relief of pain like that associated with sprains, strains, bruises or sports injuries?

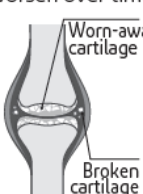
No.
Do not use for strains, sprains, bruises, or sports injuries. This product has not been shown to work for these types of injuries. It's intended only for the temporary relief of arthritis pain.

How quickly will Voltaren Arthritis Pain work for arthritis pain?
Voltaren Arthritis Pain 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 Voltaren Arthritis Pain used for?
Voltaren Arthritis Pain 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.



Healthy cartilage



Worn-away cartilage




Broken cartilage

How does Voltaren Arthritis Pain work?
Diclofenac sodium, the medicine in Voltaren Arthritis Pain, is a nonsteroidal anti-inflammatory drug (NSAID). NSAIDs are used to treat pain from medical conditions such as arthritis. Voltaren Arthritis Pain 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 Voltaren Arthritis Pain 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 Voltaren Arthritis Pain differ from prescription Voltaren Gel?
Over-the-counter Voltaren Arthritis Pain is the same strength and formula as original full prescription strength Voltaren Gel but is available without a prescription.

Apply Voltaren Arthritis Pain 4 times a day to ensure you get the full effect of the medicine.


Can I apply Voltaren Arthritis Pain to upper and lower body areas at the same time?
Yes.
You can use Voltaren Arthritis Pain 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
Knee and ankle



Upper/Lower body
Wrist and ankle



Lower body
(L)Knee and (R)knee

Do not use Voltaren Arthritis Pain on more than 2 body areas at once.

Can I apply Voltaren Arthritis Pain 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 Voltaren Arthritis Pain on my spine, hips, or shoulders?
No.
The use of Voltaren Arthritis Pain on the spine, hips, and shoulders has not been studied.

Can I take any other pain medications with Voltaren Arthritis Pain?
Ask your doctor or pharmacist before using Voltaren Arthritis Pain 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 Voltaren Arthritis Pain?
Taking other pain medications is generally not recommended. Speak with your doctor or pharmacist before taking other pain medications when using Voltaren Arthritis Pain.

How long can I use Voltaren Arthritis Pain?
Use Voltaren Arthritis Pain 4 times a day every day for up to 21 days for treatment of arthritis pain or as directed by your doctor.
Voltaren Arthritis Pain 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 Voltaren Arthritis Pain into a complete program to help manage your arthritis pain.

What do I do if I get Voltaren Arthritis Pain 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 Voltaren Arthritis Pain?
If you forget to apply Voltaren Arthritis Pain, don't double your dose. Just apply the next dose as scheduled.

How should I store Voltaren Arthritis Pain?

- Store at 20-25°C (68-77°F).
- Do not freeze Voltaren Arthritis Pain.
- Store the dosing card with your Voltaren Arthritis Pain.
- Keep out of reach of children.

Helpful Tip: If you forget to apply Voltaren Arthritis Pain, don't double your dose. Just apply the next dose as scheduled.

Additional Questions?
Call the Voltaren Arthritis Pain consumer hotline at 1-855-297-3031.
www.voltaren.com

DOCUMENT FONT SIZES	
BODY COPY	10 pt. / Diclofenac Sodium Family
HEADINGS	Min 7 pt. / Diclofenac Sodium Family & Voltaren Arthritis Pain Family
TITLE COPY	10 pt. / Diclofenac Sodium Family

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
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