

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### VOLTAREN FORTE

2% gel

DICLOFENAC-DIETHYLAMINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What VOLTAREN FORTE 2% is and what it is used for
2. Before you take VOLTAREN FORTE 2%
3. How to use VOLTAREN FORTE 2%
4. Possible side effects
5. How to store VOLTAREN FORTE 2%
6. Further information

#### *1. WHAT VOLTAREN FORTE 2% IS AND WHAT IT IS USED FOR*

VOLTAREN FORTE 2% contains active ingredient diclofenac diethylamine, which belongs to a class of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It is especially designed for rubbing into the skin and has the property of increased penetration into the skin. The active substance acts at deep inflamed tissues.

Voltaren Forte 2% is applied to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles.

#### **Voltaren Forte 2% can be used to treat:**

- injuries of muscles and joints (eg, sprains, dislocations, bruises)- it quickly relieves pain, including moderate to severe pain and contributes to the recovery and return to normal function.

## 2. BEFORE YOU TAKE VOLTAREN FORTE 2%

### **Do not take VOLTAREN FORTE 2%**

- If you are allergic (hypersensitive) to diclofenac or other medicines for the treatment of pain, fever or inflammation, such as ibuprofen or acetylsalicylic acid (a substance that is also used to prevent blood clotting) or other ingredients of this medicine (see section 6. Further information and the end part 2). If you are not sure, ask your doctor or pharmacist.

Symptoms of an allergic reaction may include: wheezing or shortness of breath (asthma); skin rash with blisters or hives; swelling of the face or tongue; runny nose.

- If you are taking diclofenac tablets or other anti-inflammatory drugs that are applied orally
- If you are in the last trimester of pregnancy.
- If you are younger than 14 years

### **Take special care with VOLTAREN FORTE 2%**

- Do not use Voltaren Forte 2% on skin with cuts, open wounds, rashes or eczema. If after applying the gel rash develops, stop applying Voltaren Forte 2%.
- Avoid applying gel on large areas of skin and over a prolonged period of time unless you have been advised by your doctor.
- Applying the gel on large areas of skin for longer periods or application of more than the recommended dose may cause side effects including disturbances in the digestive system and bleeding, irritability, fluid retention, inflammation of the liver, kidney failure, allergic reactions, shortness of breath, skin lesions.
- Voltaren Forte 2% is intended only for external use. Do not take by mouth. Do not swallow it. After application wash your hands. Make sure that it does not get in the eyes. If this happens, wash them thoroughly with clean water. If uncomfortable feeling persists, consult a doctor or pharmacist.
- You may use orthoses or bandages that are commonly applied in injuries such as sprains, but do not apply the gel under impermeable (plastic) bandages.
- The skin can become more sensitive to sunlight. Be careful if you plan to expose skin to the sun.
- If you have or have had a peptic ulcer (damage to the stomach lining), bleeding in the gastrointestinal tract, kidney problems, or liver problems, certain blood disorders or inflammatory bowel disease, consult your doctor.

Children (under 14 years)

There is insufficient data on safety and efficacy of action of this medicine in children younger than 14 years (see section " Do not use Voltaren Forte 2% ").

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Pregnancy and breastfeeding**

Contact your doctor or pharmacist for advice before using any medicine.

Do not use Voltaren Forte 2% during the last 3 months of pregnancy because it may harm your unborn baby or cause problems in childbirth. Voltaren Forte 2% can be applied during the first 6 months of pregnancy only if your doctor has advised so. Applied doses must be low, and duration of treatment should be as short as possible.

If you are breastfeeding, Voltaren Forte 2% can be applied only on the recommendation of a doctor, since diclofenac in small quantities passes into breast milk. Voltaren Forte 2% should not be used in the area of the breasts in mothers who are breastfeeding, or elsewhere, over large areas of the skin or over a longer period of time.

### ***Driving and using machines***

Patients who experience dizziness or other obstacles that are the consequences of the impact of the drug on the central nervous system, including vision problems, should avoid driving the vehicles and using machines during the use of Voltaren Forte 2%.

### ***Other warnings***

#### ***Voltaren Forte 2% contains:***

- propylene glycol, which in some people can cause skin irritation
- butylated hydroxytoluene, which may cause local skin reactions (eg, contact dermatitis) or irritation of the eyes and mucous membranes

### ***3. HOW TO USE VOLTAREN FORTE 2%***

For application on the skin.

For adults and children older than 14 years;

Apply Voltaren Forte 2% twice a day (morning and evening) on the painful area which will mitigate the pain for up to 12 hours.

#### ***How to use Voltaren Forte 2%;***

1. To remove the protective cap before first use, unscrew and remove the cap. With the other side of the cap pierce, turn and remove the protective cap from the tube.
2. Gently squeeze a small amount of gel from the tube and apply it to the painful or swollen area, slowly rubbing it into the skin. The required amount will vary depending on the size of the painful or swollen area; quantity range from the size of a cherry to the size of a walnut will usually suffice. You can feel a slight cooling effect when you rub the gel.
3. Wash your hands after rubbing the gel to avoid accidental contact with mouth or eyes, unless the hands are the area to be treated (see section 2).

Voltaren Forte 2% is intended for application to the skin.

#### ***Do not use Voltaren Forte 2% for longer than:***

Adults and children over 14 years:

- 2 weeks for injuries of muscles and joints (eg, sprains, dislocations, bruises)

If the pain and swelling do not improve within 7 days or if the condition worsens, consult a physician.

#### ***If you use more VOLTAREN FORTE 2% than you should***

If you apply more gel than you should, wipe off excess gel with tissue paper.

If the gel is swallowed, contact your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, VOLTAREN FORTE 2% can cause side effects, although not everybody gets them.

Some rare and very rare side effects can be serious

If you get any of the following signs of allergy, stop applying Voltaren Forte 2% and immediately contact your doctor or pharmacist:

- skin rash with blisters, hives; (May occur in 1 to 10 out of every 10,000 people)
- difficulties in breathing (wheezing), shortness of breath or a feeling of tightness in the chest (asthma); (May occur in less than 1 in 10,000 people)

- swelling of the face, lips, tongue or throat; (May occur in less than 1 in 10,000 people)

Other side effects that may occur are usually mild, transient and harmless. If you are concerned, ask your doctor or pharmacist.

**Common side effects** (may occur in 1 to 10 in every 100 people)

- Skin rash, itching, redness or burning sensation of the skin

**Very rare side effects** (may occur in fewer than 1 in every 10,000 people)

- The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blisters.

### ***Reporting of suspected side effects***

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

## ***5. HOW TO STORE VOLTAREN FORTE 2%***

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use VOLTAREN FORTE 2% after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## ***6. FURTHER INFORMATION***

### ***What VOLTAREN FORTE 2% contains***

The active ingredient is diclofenac diethylamine. 1 g of gel contains 23.2 mg of diclofenac diethylamine.

Other ingredients are: butylated hydroxytoluene (E321), carbomer, cocoyl-caprylocaprinate, diethylamine, isopropyl alcohol, liquid paraffin (E 905), macrogol cetostearyl ether, oleyl alcohol, propylene glycol (E1520), eucalyptus fragrance, and purified water.

### ***What VOLTAREN FORTE 2% looks like and contents of the pack***

Voltaren Forte 2% is a white to almost white, smooth, homogeneous gel similar to cream.

Medicine comes in packaging weighing 50 g.

### ***Regime of dispensing***

The medicine is issued without doctor's prescription.

### ***Manufacturer***

Novartis Consumer Health SA,  
Route de l'Etraz, 1260 Nyon, Switzerland