
Package leaflet: Information for the user

Voltaren Aktigo, 140 mg medicated plaster

For use in adolescents from 16 years of age and adults.
diclofenac sodium

Read all of this leaflet carefully before you start using this medicinal product because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Voltaren Aktigo is and what it is used for
2. What you need to know before you use Voltaren Aktigo
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1. What Voltaren Aktigo is and what it is used for

Voltaren Aktigo is a medicine that relieves pain. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

Voltaren Aktigo is used for the local symptomatic and short term treatment of pain associated with acute strains, sprains or bruises on the arms and legs as a result of injuries, e.g. sports injuries in adolescents from 16 years of age and adults.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you use Voltaren Aktigo

Do not use Voltaren Aktigo

- if you are **allergic** to **diclofenac** or any of the **other ingredients** of this medicine (listed in section 6);
- if you are **allergic** to any **other non-steroidal anti-inflammatory drug** (NSAID, e.g. acetylsalicylic acid or ibuprofen);
- if you have **ever developed asthma, hives or swelling and irritation inside the nose** after taking acetylsalicylic acid or any other NSAID;
- if you are suffering from an active **stomach or duodenal ulcer**;
- if you are in the last three months of pregnancy;
- if you are a child or an adolescent younger than 16 years of age.

Do not use Voltaren Aktigo on injured skin (e.g. skin abrasions, cuts, burns), **infected skin or skin affected by exudative dermatitis or eczema**;

Warnings and precautions

Talk to your doctor or pharmacist before using Voltaren Aktigo

- If you suffer or have previously suffered from bronchial asthma or allergies; you may experience a bronchial muscle cramp (bronchospasm), which makes breathing difficult
- if you **notice a skin rash** that develops after applying the medicated plaster. If this happens, immediately remove the medicated plaster and stop the treatment.
- if you suffer from disorders of the **kidneys, heart or liver**, or if you suffer or have previously suffered from a **stomach or intestinal ulcer** or **intestinal inflammation** or a **tendency to bleeding**.

Side effects can be reduced by using the lowest effective dose for the shortest possible period of time.

IMPORTANT precautions

- Ⓢ The medicated plaster must not come into contact with or be applied to the eyes or mucous membranes.
- Ⓢ Elderly patients should use Voltaren Aktigo with caution because they are more likely to experience side effects.

After taking off the medicated plaster, avoid exposing the treated area to direct sunlight or solarium radiation in order to reduce the risk of sensitivity to light.

Children and adolescents

Voltaren Aktigo should not be used in children and adolescents under 16 years of age because no adequate experience is available for this age group.

Other medicines and Voltaren Aktigo

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Provided that Voltaren Aktigo is used correctly, only a small amount of diclofenac is absorbed into the body so that the interactions described for diclofenac-containing medicines taken orally are unlikely to happen.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

In the last trimester of pregnancy, Voltaren Aktigo must not be used because an increased risk of complications for the mother and the child cannot be ruled out (see "Do not use Voltaren Aktigo").

In the first and second trimesters of pregnancy or if you want to become pregnant, Voltaren Aktigo should be used only after talking to your doctor.

Breast-feeding

Small quantities of diclofenac pass into the breast milk.

Talk to your doctor before using Voltaren Aktigo during breast-feeding. In any case, if you are breast-feeding Voltaren Aktigo should not be applied directly onto the breast area.

Driving and using machines

Voltaren Aktigo has no influence on your ability to drive and use machines.

3. How to use Voltaren Aktigo

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one medicated plaster twice daily.

Attach one medicated plaster to the painful area twice daily, in the morning and in the evening. The maximum total daily dose is 2 medicated plasters, even if there is more than one injured area to be treated. Treat only one painful area at once.

Use in children and adolescents

Voltaren Aktigo is contraindicated for use in children and adolescents under 16 years of age. There are insufficient data of efficacy and safety available for children and adolescents below 16 years (see section 2).

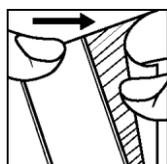
In adolescents aged 16 years and over, if this medicine is required for more than 7 days for pain relief or if the symptoms worsen your child/you is/are advised to consult a doctor.

Method of administration

For treatment on the skin (cutaneous) use only.

Instructions for use:

1. Tear open the envelope containing the medicated plaster on the notch and remove the medicated plaster



To apply the plaster:

2. Remove one of the two protective films.



3. Apply to the area to be treated and remove the remaining protective film.



4. Apply slight pressure with the palms of your hand until complete adhesion to the skin is achieved.



To remove the plaster:

5. Moisten the plaster with water and peel away an edge of the plaster and pull smoothly away from the skin.

6. To remove any product residues, wash the affected area with water gently rubbing the area with your fingers using a circular movement.

If necessary, the medicated plaster can be held in place using a net bandage. Use the medicated plaster only on intact non-diseased skin.

Do not use the medicated plaster together with an air-tight (occlusive) bandage. Do not wear it when bathing or showering.

You should not divide the medicated plaster.

Duration of use

Do not use Voltaren Aktigo for longer than 7 days.

If symptoms worsen or persist for longer than 7 days, you should consult a doctor.

If you have the impression that the effect of Voltaren Aktigo is too strong or too weak, please talk to your doctor or pharmacist.

If you use more Voltaren Aktigo than you should

Please tell your doctor if significant side effects occur after incorrect use of this medicine or accidental overdose (e.g. in children). They will be able to advise you of any action that may need to be taken.

If you forget to use Voltaren Aktigo

Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop using the plaster if you notice any of the following: sudden itchy rash (hives); swelling of the hands, feet, ankles, face, lips, mouth or throat; difficulty breathing; drop in blood pressure or weakness.

You may experience the following side effects:

Common side effects (may affect up to 1 in 10 people):

local skin reactions, such as skin redness, burning sensation, itching, inflamed skin redness, skin rash, sometimes with pustules or wheals.

Very rare side effects: may affect up to 1 in 10,000 people:

hypersensitivity reactions or local allergic reactions (contact dermatitis).

In patients externally using drugs from the same drug group as diclofenac, there have been isolated reports of generalised skin rash, hypersensitivity reactions such as swelling of the skin and mucous membranes and anaphylactic-type reactions with acute circulatory regulation disorders and light sensitivity reactions.

Absorption of diclofenac into the body by the skin is very low compared to the drug concentration in the blood following oral use of diclofenac. Therefore, the likelihood of side effects occurring in the body as a whole (such as gastrointestinal, hepatic or kidney disturbances or difficulty breathing) is very low.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Voltaren Aktigo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the sachet after "EXP". The expiry date refers to the last day of that month.

Store below 30°C.

Store in the original package in order to protect from desiccation and light. Keep the sachet tightly closed in order to protect from desiccation and light.

Do not use Voltaren Aktigo if you notice that it is damaged.

Used plasters should be folded in half with the sticky side inwards.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Voltaren Aktigo contains

- The active substance is diclofenac sodium.
Each medicated plaster contains 140 mg diclofenac sodium.
- The other ingredients are:

Supporting layer: Polyester non-woven fabric

Adhesive layer: Basic butylated methacrylate copolymer, Copolymer acrylate vinyl acetate, PEG 12stearate, Sorbitan oleate

Liner: Mono silicone coated paper

What Voltaren Aktigo looks like and contents of the pack

Voltaren Aktigo are white 10x14 cm sized self-adhesive plasters made of non-woven fabric on one and paper on other side.

Voltaren Aktigo is available in packs of 2, 5 and 10 plasters, each in a single sachet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline Dungarvan Limited
Knockbrack
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