



# Voltarol

**ONE A DAY Muscle Pain Relief  
140mg Medicated Plaster**



Diclofenac Sodium

- **Effective pain relief • Ultra-thin and discreet**
- **24h release of a potent anti-inflammatory agent**

**Read all of this leaflet carefully before you start using this medicine 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. See section 4.
- 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 Voltarol ONE A DAY Medicated Plaster is and what it is used for
2. What you need to know before you use Voltarol ONE A DAY Medicated Plaster
3. How to use Voltarol ONE A DAY Medicated Plaster
4. Possible side effects
5. How to store Voltarol ONE A DAY Medicated Plaster
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**1. What Voltarol ONE A DAY Medicated Plaster is and what it is used for**

Voltarol ONE A DAY Medicated Plaster is a medicine that relieves pain. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

Voltarol ONE A DAY Medicated Plaster is used for the local symptomatic short-term treatment (max. 7 days) of pain associated with acute strains, sprains or bruises on the arms and legs as a result of blunt injuries in adolescents from 16 years of age and adults.

**2. What you need to know before you use Voltarol ONE A DAY Medicated Plaster**

**Do not use Voltarol ONE A DAY Medicated Plaster**

- 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 attacks, 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**;
- **on injured skin** (e.g. skin abrasions, cuts, burns), **infected skin or skin affected by inflammation (exudative dermatitis) or eczema**.
- if you are in the last three months of pregnancy;
- if you are a child or an adolescent younger than 16 years of age.

**Warnings and precautions**

Talk to your doctor or pharmacist before using Voltarol ONE A DAY Medicated Plaster

- 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 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 Voltarol ONE A DAY Medicated Plaster 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.

Do not use Voltarol ONE A DAY Medicated Plaster at the same time as any other diclofenac-containing or other non-steroidal pain-relieving and anti-inflammatory medicines regardless of whether these are used externally or taken by mouth.

**Children and adolescents**

Diclofenac 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 **Do not use Voltarol ONE A DAY Medicated Plaster**).

**Other medicines and Voltarol ONE A DAY Medicated Plaster**

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

Provided that Voltarol ONE A DAY Medicated Plaster 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 and breast-feeding**

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 first and second trimesters of pregnancy or if you want to become pregnant, Voltarol ONE A DAY Medicated Plaster should be used only after talking to your doctor.

In the last trimester of pregnancy, Voltarol ONE A DAY Medicated Plaster must not be used because an increased risk of complications for the mother and the child cannot be ruled out (see "Do not use Voltarol ONE A DAY Medicated Plaster").

Breast-feeding

Small quantities of diclofenac pass into the breast milk.

Talk to your doctor before using Voltarol ONE A DAY Medicated Plaster during breast-feeding. In any case, if you are breast-feeding Voltarol ONE A DAY Medicated Plaster should not be applied directly onto the breast area.

Oral forms (e.g. tablets) of diclofenac can cause adverse effects in your unborn baby. It is not known if the same risk applies to diclofenac when it is used on the skin.

**Driving and using machines**

Voltarol ONE A DAY Medicated Plaster has no influence on your ability to drive and use machines.

**Voltarol ONE A DAY Medicated Plaster contains butylated hydroxyanisole (E320)**

Butylated hydroxyanisole may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

**3. How to use Voltarol ONE A DAY Medicated Plaster**

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.

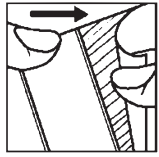
The recommended dose is one medicated plaster once daily. Attach one medicated plaster to the painful area. The maximum total daily dose is 1 medicated plaster a day, even if there is more than one injured area to be treated. Treat only one painful area at once.

#### Method of administration

For application on the skin (cutaneous use).

Instructions for use:

1. Cut the sachet along the dotted line 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 Voltarol ONE A DAY Medicated Plaster for longer than 7 days.

If this medicine is required for more than 7 days for pain relief or if the symptoms worsen you are advised to consult a doctor.

#### If you use more Voltarol ONE A DAY Medicated Plaster 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). He will be able to advise you of any action that may need to be taken.

#### If you forget to use Voltarol ONE A DAY Medicated Plaster

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 or pharmacist.

#### 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 medicines from the same active substance 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 concentration of active substance in the blood following oral use of diclofenac. Therefore, the likelihood of side effects occurring in the body as a whole (such as gastrointestinal 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 the Yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Voltarol ONE A DAY Medicated Plaster

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 carton and the sachet after "EXP". The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

Do not use Voltarol ONE A DAY Medicated Plaster 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 Voltarol ONE A DAY Medicated Plaster contains

- The active substance is diclofenac sodium. Each medicated plaster contains diclofenac as 140 mg diclofenac sodium.
- The other ingredients are:
  - Backing layer: Polyester non-woven fabric
  - Adhesive layer: Polyacrylate dispersion, Tributyl citrate, Butylhydroxyanisole
  - Protective liner: Mono silicone coated paper

##### What Voltarol ONE A DAY Medicated Plaster looks like and contents of the pack

Voltarol ONE A DAY Medicated Plaster is a white 10x14 cm sized self-adhesive medicated plaster made of non-woven fabric on one and paper on other side.

Voltarol ONE A DAY Medicated Plaster is available in packs of 2, 5, 7 and 10 medicated plasters, each in a single sachet.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder

Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K.

##### Manufacturer

Fidia farmaceutici S.p.A., Via Ampere, 29, 20037 Paderno Dugnano (MI), Italy or GlaxoSmithKline Consumer Healthcare, GmbH & Co. KG, Barthstraße 4, 80339 München, Germany.

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