

Package leaflet: Information for the user

Itami 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 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 Itami is and what it is used for
2. What you need to know before you use Itami
3. How to use Itami
4. Possible side effects
5. How to store Itami
6. Contents of the pack and other information

1. What Itami is and what it is used for

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

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

2. What you need to know before you use Itami

Do not use Itami

- 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 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 Itami

- 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 Itami 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 Itami 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.

Other medicines and Itami

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

Provided that Itami 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 breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- During the first and second trimester of pregnancy, Itami should not be used unless clearly necessary.
- Do not use Itami during the last three months of pregnancy as it could harm the unborn child or cause problems during delivery. The use of diclofenac is contraindicated in the third trimester of pregnancy.
- Small quantities of diclofenac pass into the breast milk. When breastfeeding, only use Itami if recommended to do so by your doctor or pharmacist. If you are breast-feeding, Itami should not be applied directly onto the breast area.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3. How to use Itami

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.

Adults and adolescents aged 16 years and older should attach one medicated plaster to intact non-diseased skin at 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. Itami is to be used for the shortest duration necessary to control symptoms. **If this medicine is required for more than 7 days for pain relief or if the symptoms worsen, it is recommended to consult a doctor.**

Use in children and adolescents

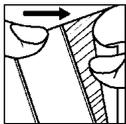
Itami is contraindicated for use in children and adolescents under 16 years of age. There are insufficient data of efficacy and safety available for children and adolescents below 16 years (see section 2).

Elderly

Older people tend to be more at risk of the side effects of NSAIDs, Itami should be used in caution in elderly patients.

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 Itami 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 Itami is too strong or too weak, please talk to your doctor or pharmacist.

If you use more Itami 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 Itami

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.

Rare (may affect up to 1 in 1,000 people):

Dry skin

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

hypersensitivity reactions or local allergic reactions (contact dermatitis), asthma, photosensitivity reactions.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Itami

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.

Do not store above 30 °C.

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

Do not use Itami 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 Itami 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:
Basic butylated methacrylate copolymer
Acrylate copolymer
PEG 12 stearate
Sorbitan oleate

Protective liner:
Mono silicone coated paper

What Itami looks like and contents of the pack

Itami is a white 10 x 14 cm sized self-adhesive plaster made of non-woven fabric on one and paper on other side.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fidia Farmaceutici S.p.A., Via Ponte della Fabbrica, 3/A - 35031 Abano Terme (PD), Italy

Manufacturer

IBSA Farmaceutici Italia Srl, S.S. 11 Padana Superiore km 160, Cassina de' Pecchi (MI), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

DE: Diclofenac Fidia 140 mg wirkstoffhaltiges Pflaster
BE: Diclofenac Patch EG 140 mg emplâtre médicamenteux / Diclofenac Patch EG 140 mg pleister
AT: Voltadol Schmerzpfaster 140 mg wirkstoffhaltiges Pflaster
IE: Itami 140 mg medicated plaster
LU: Diclofenac Patch EG 140 mg emplâtre médicamenteux / Diclofenac Patch EG 140 mg wirkstoffhaltiges Pflaster
SI: Itami 140 mg zdravilni obliž
SK: Itami 140 mg liečivá náplast'

This leaflet was last revised in