BEFORE USE, CAREFULLY READ ALL THE INFORMATION GIVEN ON THE INFORMATIVE LEAFLET

This medicinal product is intended for SELF-MEDICATION. It can be used to treat mild, temporary problems that are easily recognised and solved with no need for medical assistance.

It can therefore be bought without a prescription but should be used correctly to ensure its efficacy and to reduce side effects.

- Ask your pharmacist for more information and advice.
- Seek medical advice if the problem is not solved after a short period of treatment.

Ingredients
Each medicated plaster contains:

Active ingredient: diclofenac sodium 140 mg

Excipients: basic butylated methacrylate copolymer; acrylic vinyl acetate copolymer; polyethylene glycol 12 stearate; sorbitan oleate; non-woven fabric; silicone paper.

Presentation
ITAMI comes as a medicated, self-adhesive plaster measuring 10 x 14 cm
The product is available in packs of 5, 10 and 15 plasters, each individually packaged.

What it is
A non-steroidal anti-inflammatory drug for use on skin. ITAMI is used to treat muscle and joint pain at the affected site.

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

Manufacturer and final controller
SPA Italiana Laboratori Bouty, S.S. 11 Padana Superiore km 160, Cassina de’ Pecchi (MI)

Why use it
ITAMI is used for the topical treatment of rheumatic or traumatic pain and inflammation of the joints, muscles, tendons and ligaments.

When not to use it
- Hypersensitivity to diclofenac, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs) or to any of the excipients in the finished product.
- Patients who have suffered asthmatic attacks, itching or acute rhinitis after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Damaged skin, regardless of the type of lesion: exudative dermatitis, eczema, infected lesion, burns or cuts.
- Third trimester of pregnancy (see paragraph "What to do when pregnant or breastfeeding").
- Patients with active peptic ulcer.

*Children and adolescents:*

Not recommended for use by children and adolescents under the age of 16 years old.

**What to do when pregnant or breastfeeding**

Consult a doctor and only use ITAMI having fully assessed the risks/benefits in question. Consult a doctor even if pregnancy is only suspected or if you are planning to fall pregnant.

**Pregnancy**

Systemic concentration of diclofenac, when compared with oral formulations, is lower after topical administration. The following recommendations are made with reference to experience with treatment with NSAIDs by systemic administration:

The inhibition of prostaglandin synthesis may have a negative effect on pregnancy and embryo/foetal development. Results of epidemiological studies suggest that there may be an increased risk of abortion and heart malformation and gastroschisis after use of a prostaglandin synthesis inhibitor during the early stages of pregnancy. The absolute risk of heart malformation increased from less than 1% to approximately 1.5%.

It has been considered that the risk increases with the dosage and duration of therapy. In animals, the administration of prostaglandin synthesis inhibitors has been shown to cause increased pre- and post-implant loss and embryo-foetal mortality.

Additionally, an increased incidence of various malformations, including cardiovascular malformations, has been reported in animals to which prostaglandin synthesis inhibitors were administered during the organogenetic period.

During the first and second trimesters of pregnancy, diclofenac must only be administered if strictly necessary. If diclofenac is used in a woman seeking to conceive or during the first and second trimester of pregnancy, the dose must be kept as low as possible and treatment must be for the shortest possible duration.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors can expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the arterial duct and pulmonary hypertension);
- kidney dysfunction, which can progress to kidney failure with oligohydramnios
  - the mother and the baby, at the end of pregnancy, to:
    - possible lengthening of bleeding time and anti-aggregating effect that can also occur at very low doses;
    - inhibition of uterine contractions resulting in delayed or prolonged labour.

Diclofenac is consequently not recommended during the third trimester of pregnancy.

**Breastfeeding**

As other NSAIDs, diclofenac is transmitted in small quantities into the mother's milk. However, at the therapeutic doses of ITAMI, there should be no effect on the baby. Due to the lack of controlled studies in breastfeeding women, the product must only be used when breastfeeding if recommended by a health professional. In this situation, ITAMI must not be applied to the breasts of breastfeeding mothers, nor anywhere else on extended areas of skin or for a prolonged period of time.

**Precautions for use**

If the diclofenac medicated plasters are used over large areas of skin for a prolonged period of time, we cannot exclude possible systemic side effects.

The medicated plaster must only be applied to unbroken, healthy skin; it must not be applied to injured skin or open wounds. Plasters must not come into contact with eyes or mucous membranes and must not be ingested.
Side effects can be minimised by using the smallest dose required for an effective control of symptoms for the shortest duration of treatment possible. Do not use with an occlusive bandage preventing air from passing.

ITAMI must be used with caution in patients who have experienced previous reactions from hypersensitivity to NSAIDs or painkillers, e.g. asthma attacks, skin eruptions, acute allergic rhinitis and anaphylactoid reactions. Asthmatic patients suffering from chronic obstructive disease of the lungs, allergic rhinitis or inflammation of the nasal mucous (nasal polyp) react with asthmatic attacks, local inflammation of the skin or mucous (Quincke oedema) or itching to treatment with NSAIDs more frequently than other patients.

Administration of ITAMI should be suspended in women with fertility problems or undergoing fertility examinations. Treatment must be interrupted immediately if a skin rash develops after application of the medicated plaster. Do not administer any other medicinal product based on diclofenac or other NSAIDs at the same time.

Although systemic effects should be minor, the medicated plaster should be used with caution in patients suffering from kidney, heart or liver disease, with a history of peptic ulcer or intestinal inflammatory disease or bleeding diathesis. Non-steroidal anti-inflammatory drugs must be used with special care in elderly patients, who are more likely to suffer side effects. Patients must be warned to avoid exposure to direct sunlight or to tanning lamps for approximately one day after removing the medicated plaster in order to reduce the risk of photosensitivity.

**Medicinal products and foodstuffs that may alter the effect of the medicinal product**

As the systemic absorption of diclofenac following the use of medicated plasters is very low, the risk of developing clinically significant interactions with other medicinal products is negligible.

In any case, if using high doses of the medicinal product or if using it for long periods of time or taking other medicinal products, please seek advice from your doctor or pharmacist. Do not use other topical or systemic drugs containing diclofenac or other NSAIDs at the same time.

**It is important to know that**

Use of products for topical application, particularly if prolonged, can give rise to sensitisation. In this case, treatment must be interrupted and medical advice sought to identify appropriate therapy. This medicinal product should not be used for prolonged periods of treatment. After a short period of treatment with no appreciable results, seek medical advice. The application of ITAMI medicated plasters does not affect your ability to drive or use machinery.

**How to use this medicinal product**

*For cutaneous use only.*

**Dosage**

The product must only be applied to unbroken, healthy skin; it must not be applied when bathing or showering.

The diclofenac medicated plaster must be used for the shortest possible time in relation to the recommended use.

**How much**

*Adults*

Unless otherwise medically prescribed, apply one plaster twice a day.
Warning: do not exceed the recommended doses unless instructed to do so by the doctor or pharmacist.

- **When and for how long**
  Apply one plaster every 12 hours to the skin of the area to be treated.
  Use for up to 14 days.
  If no improvement is seen following the recommended treatment period, seek medical advice (see the paragraph "Precautions for use").

*Children and adolescents under 16 years old:*
This medicated plaster is not recommended for use in children and adolescents aged under 16 years old because insufficient data is available to assess the safety and efficacy of the drug (see the paragraph "When not to use it").
In adolescents aged 16 years old or over, if the product is required for treatment exceeding 7 days to relieve pain or if symptoms worsen, the patient or relatives of the adolescent should seek medical advice.

*The elderly*
This medicinal product must be used with caution in elderly patients, as they are more likely to suffer side effects (see the paragraph "Precautions for use").

*Patients with liver or kidney failure*
For the use of diclofenac medicated plasters in patients with liver or kidney failure, refer to the paragraph "Precautions for use".
WARNING: DO NOT EXCEED THE RECOMMENDED DOSE EXCEPT ON MEDICAL ADVICE. ONLY USE FOR SHORT PERIODS OF TIME.

- **How**
  **Instructions for use:**
  1. Cut the packaging along the dotted line and remove the plaster.

  **Applying the plaster:**
  2. Remove one of the two protective leafs.
  3. Apply to the area to be treated and remove the remaining protective leaf.
  4. Apply gentle pressure with the palm of the hand until it has completely adhered to the skin.

  **Removing the plaster:**
  5. Dampen the plaster with water and lift one flap, pulling gently.
  6. Wash the area concerned with water, making circular movements with fingers to eliminate any product residues.

  Topical diclofenac can be used with non-occlusive bandages; it may not be used with occlusive bandages that prevent air from passing.
  Plasters must be used whole.

**What to do if you have taken too much medication**
No cases of overdose with diclofenac medicated plasters have been reported. Should any systemic side effects occur due to incorrect use or accidental overdose (e.g. in children) with the product, we recommend taking the general support measures applicable in the event of intoxication from non-steroidal anti-inflammatory drugs.
The low systemic absorption of topical diclofenac means that overdose is highly unlikely. However, side effects similar to those seen in diclofenac tablets may be seen if topical diclofenac sodium is inadvertently ingested (1 pack of 10 medicated plasters contains the equivalent of 1.4 g of diclofenac sodium). In the event of accidental ingestion giving rise to significant systemic side effects, the general therapeutic measures usually adopted to treat poisoning with non-steroidal anti-inflammatory drugs should be taken. Gastric decontamination and the use of active carbon must be considered, particularly within a short time of ingestion.

In the event of the accidental assumption/ingestion of ITAMI, notify the doctor immediately or contact the nearest hospital.

**Side effects**

Following long-term application over large areas of skin, due to the portion of active ingredient absorbed, we cannot exclude the onset of systemic side effects, particularly on a gastroenteric level.

Side effects (Table 1) are listed in order of frequency, starting with the most frequent, using the following convention: common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000); not known: no estimate can be prepared from the data available.

<table>
<thead>
<tr>
<th><strong>Table 1</strong></th>
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<tr>
<td><strong>Infections and infestations</strong></td>
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<tr>
<td>Very rare Rash with spots</td>
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<tr>
<td><strong>Immune system disturbances</strong></td>
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<tr>
<td>Very rare Hypersensitivity (including itching), angioneurotic oedema, anaphylactoid reaction</td>
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<tr>
<td><strong>Respiratory, chest and mediastinal pathologies</strong></td>
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<tr>
<td>Very rare Asthma</td>
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<tr>
<td><strong>Skin and subcutaneous tissue pathologies</strong></td>
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<tr>
<td>Common Rash, eczema, erythema, dermatitis (including allergic dermatitis and contact dermatitis), itching</td>
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<tr>
<td>Rare Dermatitis bullosa (e.g. erythema bullosum), dry skin</td>
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<tr>
<td>Very rare Photosensitivity reaction</td>
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<tr>
<td><strong>Systemic pathologies and conditions relating to the site of administration</strong></td>
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<tr>
<td>Common Reaction at the site of administration</td>
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Use of the product in association with other drugs containing diclofenac may give rise to severe evolution skin reactions (Stevens-Johnson syndrome, Lyell syndrome).

**Compliance with the instructions contained on the informative leaflet, reduces the risk of side effects.**

Please inform your doctor or pharmacist should you experience any side effects at all with this medicine, even if not described in the informative leaflet. Request and fill in the sheet for signalling side effects, available from the chemist (model B).

**Expiry and storage**

Check the expiry date printed on the package. The expiry date refers to the unopened, correctly stored product.

Store at a temperature of no more than 30°C.

**WARNING:** Do not use this product after the expiry date specified on the packaging.
Keep all medicines out of the reach and sight of children.
It is important to have information on the medicinal product available at all times; keep both the box and informative leaflet.

Informative leaflet last reviewed by the Italian Pharmaceutical Agency:
September 2012