SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

FLECTOR TISSUGEL 140mg medicated plaster

2 Qualitative and quantitative composition

Each 140 cm^2 (10 cm x 14 cm) of medicated plaster contains a total of 180 mg of diclofenac epolamine corresponding to 140 mg of diclofenac sodium (1% w/w).

Excipients with known effect:
methyl parahydroxybenzoate (E218): 14 mg
propyl parahydroxybenzoate (E216): 7 mg
propylene glycol: 420 mg
Dalin PH perfume containing amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptine carbonate
Referred to amount per plaster.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster

White to pale yellow paste spread as a uniform layer onto unwoven support.

4.1 Therapeutic indications

Short term treatment (max. 7 days)
Local symptomatic and short term treatment of pain in acute strains, sprains or bruises of the extremities following blunt trauma, e.g. sports injuries in adolescents from 16 years of age and adults.

4.2 Posology and method of administration

Cutaneous use only

Posology

One medicated plaster should be applied to the painful area twice daily, in the morning and in the evening. The maximum daily dose is 2 medicated plasters, even if there is more than one injured area to be treated. Therefore, only one painful area can be treated at a time.
Duration of administration

The duration of use should not exceed 7 days. The therapeutic benefit of

longer use has not been established.

If there is no improvement, during the recommended duration of treatment or symptoms worsen, a doctor should be consulted.
Flector Tissugel is to be used for the shortest duration
necessary to control symptoms depending on the indication.

Elderly
This medication should be used with caution in elderly patients who are more prone to adverse events. See also Section 4.4.

Children and adolescents below 16 years
There are insufficient data on efficacy and safety available for children and adolescents below 16 years of age (see also contraindication section 4.3).
In children aged 16 years and over, if the symptoms worsen, the patient/parents of the adolescents is/are advised to consult a doctor.

Patients with hepatic or renal insufficiency
For the use of Flector Tissugel in patients with hepatic or renal insufficiency see section 4.4.

Method of administration
Cut the envelope containing the medicated plaster as indicated. Remove one medicated plaster, remove the plastic film used to protect the adhesive surface and apply it to painful joint or region. If necessary it can be held in place with an elastic net. Carefully reseal the envelope with the sliding closure.

The plaster should be used whole.

4.3 Contraindications

This medicinal product is contraindicated in the following cases:
- Hypersensitivity to diclofenac, acetylsalysilic acid or other non-steroidal anti-inflammatory drugs (NSAIDs) or any excipients of the finished medicinal product listed in section 6.1.
- Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDS)
- damaged skin, whatever the lesion involved: exudative dermatitis, eczema, infected lesion, burn or wound.
- from the beginning of the 6th month of pregnancy (see 4.6 Pregnancy and lactation).
- Patients with active peptic ulceration.
- Children and adolescents aged less than 16 years.

4.4 Special warnings and precautions for use

- The medicated plaster should be applied only to intact, non-diseased skin, and not to skin wounds or open injuries, and should not be worn when bathing or showering.

- The medicated plaster should not come into contact with or be applied to the mucosae or the eyes.
- Not for use with occlusive dressing.
- Discontinue the treatment immediately if a skin rash develops after applying the medicated plaster.
- Do not administer concurrently, by either the topical or the systemic route, any medicinal product containing diclofenac or other NSAIDs.
- The possibility of systemic adverse events from application of topical diclofénac cannot be excluded if the preparation is used over a prolonged period (see the product information on systemic forms of Diclofenac). Although systemic effects should be low, the plaster should be used with caution in patients with renal, cardiac or hepatic impairment, history of peptic ulceration or inflammatory bowel disease or bleeding diathesis. Non□steroidal anti□inflammatory drugs should be used with particular caution in elderly patients who are more prone to adverse events.
- This medicine contains:
  - propylene glycol which may cause skin irritation.
  - methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and Dalin PH perfum containing amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptine carbonate, which may cause allergic reactions (possibly delayed).
- Patients should be warned against exposure to direct and solarium sunlight in order to reduce the risk of photosensitivity.
- Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergenic disease or allergy to acetylsalicylic acid or other NSAID. The medicated plaster should be used with caution in patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other non□steroidal anti□inflammatory agents (see 4.3 Contraindications).In order to minimise the occurrence of undesirable effects it is recommended to use the lowest effective dose for the shortest duration necessary to control symptoms, without exceeding the approved maximum 14 days.(Please see section 4.2 and 4.8)

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac during labelled use of the medicated plasters is very low, the risk of developing clinically relevant drug-drug interactions is negligible.

4.6 Fertility, pregnancy and lactation

Pregnancy

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Breast-feeding

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of diclofenac medicated plaster no effects on the suckling child are anticipated.
Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Flector Tissugel should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time (see section 4.4).

4.7 Effects on ability to drive and use machines

Diclofenac medicated plaster application has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common: (>1/10); 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: cannot be estimated from the available data.

Table 1

Infections and infestations	
Very rare	Rash pustular
Immune system disorder	
Very rare	Hypersensitivity (including urticaria), angioneurotic oedema, anaphylactic type reaction
Respiratory, thoracic and mediastinal disorders	
Very rare	Asthma
Skin and subcutaneous tissue disorders *	
Common Uncommon Rare Very rare	Rash, eczema, erythema *, dermatitis (including allergic and contact dermatitis*), pruritus* petechiae * Dermatitis bullous (e.g. erythema bullosum), dry skin Photosensitivity reaction
General disorders and administration site conditions *	
Common Uncommon	Application site reactions * Feeling hot

*Adverse reactions have been reported in a clinical trial, where 1252 patients were treated with Flector Tissugel medicated plaster and 734 with Placebo in clinical trials.

Systemic absorption of diclofenac is very low compared with plasma levels obtained following administration of oral forms of diclofenac and the likelihood of systemic side effects reactions (like gastric, hepatic and renal disorders) occurring with topical diclofenac is very small compared with the frequency of side effects associated with oral diclofenac. However, where Flector Tissugel is applied to a relatively large area of skin and over a prolonged period, the possibility of systemic side effects cannot be excluded.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

There is no experience with overdose of diclofenac medicated plaster. Should systemic side effects occur due to incorrect use or accidental overdose (e.g. in children) of this product, the general measures recommended for intoxication with non-steroidal anti-inflammatory drugs should be taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory preparations, non-steroids for topical use.

ATC Code: M02AA15

Diclofenac hydroxyethylpyrrolidine or diclofenac epolamine is a water soluble salt of diclofenac.

Diclofenac is a nonsteroidal anti-inflammatory drug derived from phenylacetic acid which belongs to the aryl carboxylic acid group of compounds.

In the form of a medicated plaster, it has topical anti-inflammatory and analgesic activity.

5.2 Pharmacokinetic properties

Following cutaneous application of the medicated plaster, diclofenac epolamine is absorbed through the skin.

The absorption kinetics at steady state show a prolonged release of the active ingredient with a maximum diclofenac plasma level (Cmax) of 17.4 ±13.5ng/ml, which is reached after about 5 hours (Tmax 5.4±3.7 hours).

Diclofenac is extensively bound to plasma protein (about 99%).

Systemic transfer in healthy volunteers when using the medicated plaster, compared with oral forms of diclofenac, is of the order of 2%, as estimated from the urinary excretion of the drug and its metabolites and from a between study comparison.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans, beyond the information included in other sections of the SPC. In the rat and rabbit, diclofenac epolamine and epolamine monosubstance have caused embryotoxicity and increased embryolethality after oral use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Supporting layer:
Unwoven polyester support.

Adhesive layer (active gel):
Gelatin, povidone (K90), liquid sorbitol (non crystallising), heavy kaolin, titanium dioxide (E171), propylene glycol, methyl parahydroxybenzoate(E218), propyl parahydroxybenzoate(E216), disodium edetate(E385), tartaric acid, aluminium glycinate, carmellose sodium, sodium polyacrylate, 1,3-butylene glycol, polysorbate 80, Dalin PH perfume (containing amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptine carbonate), purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

After first opening the sealed envelope: 3 months

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

Sealed envelopes made of paper/PE/aluminium/ethylene and methacrylic acid copolymer contain 2 or 5 medicated plasters.

Pack size: 2, 5, 10 and 14 medicated plasters per box.

Not all pack size may be marketed.

6.6 Special precautions for disposal

Remaining active ingredient of the plaster may pose a risk to the aquatic environment. Do not flush used plasters down the toilet. The plasters should be disposed of according to local requirements.

7 MARKETING AUTHORISATION HOLDER

IBSA Farmaceutici Italia S.r.l
Via Martiri di Cefalonia 2,
26900 Lodi - Italy

8 MARKETING AUTHORISATION NUMBER(S)

PL 21039/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/03/2006 / 31/03/2010

10 DATE OF REVISION OF THE TEXT

26/10/2021