Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diclofenac 140 mg 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 CLINICAL PARTICULARS

4.1 Therapeutic indications

Local symptomatic treatment of pain in epicondylitis and ankle sprain in adolescents from 16 years of age and adults.

4.2 Posology and method of administration

Cutaneous use only
Posology
Adults and adolescents 16 years and older

- Symptomatic treatment of ankle sprains: 1 application a day
- Symptomatic treatment of epicondylitis: 1 application morning and evening.

Duration of administration
Diclofenac is to be used for as short as possible depending on the indication:

- Symptomatic treatment of ankle sprains: 3 days
- Symptomatic treatment of epicondylitis: max. 14 days.

If there is no improvement, during the recommended duration of treatment or symptoms worsen, a doctor should be consulted.

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 product is required for more than 7 days for pain relief or 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 Diclofenac 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 medicinal product contains

- 420 mg propylene glycol in each medicated plaster.
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).
- Fragrance with 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. These allergens may cause allergic reactions.

- 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

In view of the low rate of systemic transfer during normal use of the medicated plasters, the drug interactions reported for oral diclofenac are unlikely to be observed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is insufficient experience for the use during pregnancy. Animal studies have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown. Therefore Diclofenac should not be used during first and second trimester, and is contra-indicated from the beginning of the 6th month of pregnancy.
During the last trimester of pregnancy, the use of prostaglandine synthetase inhibitors may result in:

- Inhibition of uterine contractions, prolongation of pregnancy and delivery
- Pulmonary and cardiac toxicity in the foetus (pulmonary hypertension with preterm closing of the ductus arteriosus)
- Renal insufficiency in the foetus with oligohydramnios
- Increase possibility of bleeding in the mother and child and increased oedema formation in the mother.

Lactation

Experimental data regarding excretion of diclofenac epolamine in human or animal milk are not available therefore, Diclofenac is not recommended in nursing mothers.

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	Rash, eczema, erythema *, dermatitis (including allergic and contact dermatitis*), pruritus*
Uncommon	petechiae *
Rare	Dermatitis bullous (e.g. erythema bullosum), dry skin
Very rare	Photosensitivity reaction
General disorders and administration site conditions *	
Common	Application site reactions *
Rare	Feeling hot
*Adverse reactions have been reported in a clinical trial, where 1252 patients were treated with Diclofenac 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 Diclofenac medicated plaster 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 HPRA Pharmacovigiliance. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

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 ±13.5 ng/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 25°C.

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 sizes 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 (LO)
Italy

8 MARKETING AUTHORISATION NUMBER

PA1104/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th October 2022

10 DATE OF REVISION OF THE TEXT

January 2023