Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diclomel 140 mg medicated plaster

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated plaster contains 140 mg diclofenac sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster

100 mm * 140 mm sized rectangular plaster composed of adhesive colourless to pale yellow matrix sandwiched between a white polyester backing and a siliconized transparent release liner.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adults and adolescents from 16 years of age
One medicated plaster should be applied to the painful area, 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 use
Diclomel 140 mg medicated plaster is for short-term treatment.
The medicinal product is to be used for the shortest duration necessary to control symptoms.
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 a worsening of symptoms, a doctor should be consulted.

Elderly patients and patients with renal or hepatic impairment
This medicinal product should be used with caution in elderly patients who are more prone to adverse events (see also section 4.4).

For the treatment of elderly and patients with renal or hepatic impairment see section 4.4.

Paediatric population
There are insufficient data on efficacy and safety available for children and adolescents below 16 years of age (see also section 4.3).

In adolescents aged 16 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen, the patient/parents of the adolescent is/are advised to consult a doctor.

Method of administration
Cutaneous use.
The medicated plaster should be applied only to intact non-diseased skin and should not be worn when bathing or showering.
The medicated plaster should not be divided.

If necessary, the medicated plaster can be held in place using a net bandage.
The medicated plaster must not be used together with an occlusive dressing.

4.3 Contraindications

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- in patients with hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs [NSAIDs]
- in patients who have previously experienced an asthma attack, angioedema, urticaria or acute rhinitis when taking acetylsalicylic acid or any other non-steroidal anti-inflammatory drugs (NSAIDs)
- in patients with active peptic ulcer
- on damaged skin, whatever the lesion involved: exudative dermatitis, eczema, infected lesion, burn or wound
- third trimester of pregnancy (see section 4.6)
- use in children and adolescents aged less than 16 years.

4.4 Special warnings and precautions for use

The medicated plaster must not come into contact with or be applied to the eyes or mucous membranes. It should be applied only to intact non-diseased skin, and not to skin wounds or open injuries.

Topical diclofenac can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
Undesirable effects can be reduced by using the lowest effective dose for the shortest possible period of time (see section 4.2).

Bronchospasm can occur in patients who suffer or have previously suffered from bronchial asthma or allergies.

Treatment must be stopped immediately if a skin rash develops after applying the medicated plaster.

Patients should be warned against exposure to sunlight or solarium radiation after removal of the medicated plaster in order to reduce the risk of photosensitisation.

The possibility of systemic adverse events from application of diclofenac medicated plaster cannot be excluded if the medicinal product is used on large areas of skin and over a prolonged period (see the product information on systemic forms of diclofenac).

Although the systemic effects are expected to be minimal, the medicated plaster should be used with caution in patients with impaired renal, cardiac or hepatic function, or a history of peptic ulcer, inflammatory bowel disease or haemorrhagic diathesis. Non-steroidal anti-inflammatory drugs should be used with caution in elderly patients as they are more likely to experience undesirable effects.

No other medicinal products containing diclofenac or any other non-steroidal anti-inflammatory drugs (NSAIDs) should be used concomitantly, neither topically nor systemically.

Paediatric population
Diclomel 140 mg medicated plaster is contraindicated in children and adolescents under 16 years of age.

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

Fertility
There are no data available on the use of topical formulations of diclofenac and its effects on fertility in humans. The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. As for other NSAIDs, the oral use of diclofenac may impair female fertility and is not recommended in women attempting to conceive.

Pregnancy
There are no clinical data from the use of diclofenac during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic diclofenac exposure reached after topical administration can be harmful to an

embryo/foetus. With reference to experience from treatment with pharmaceutical forms 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 used 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 oligohydroamniosis

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 (see section 4.3).

Breast-feeding
Like other NSAIDs, diclofenac is excreted 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, Diclomel should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time.

4.7 Effects on ability to drive and use machines

Diclomel has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The following frequency categories are used for reporting undesirable effects:
Very common ≥ 1/10
Common ≥ 1/100 to < 1/10
Uncommon ≥ 1/1 000 to < 1/100
Rare ≥ 1/10 000 to < 1/1 000
Very rare < 1/10 000
Not known cannot be estimated from the available data

Infections and infestations
Very rare Rash pustular.

Immune system disorder
Very rare Hypersensitivity (including urticaria), angioedema, 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.
Rare Dermatitis bullous (e.g. erythema bullosum), dry skin.
Very rare Photosensitivity reaction.
Not known Burning sensation at the application site.

General disorders and administration site conditions
Common Application site reactions

Systemic plasma diclofenac levels measured during labelled use of the cutaneous patches are very low compared to those obtained after oral intake of diclofenac. The risk of developing systemically induced side effects (like gastric, hepatic and renal disorders) during use of the plaster therefore appears to be low. However, in particular when the medicated plaster is used on a large area of skin and over a prolonged period of time, systemic undesirable effects may occur.

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 Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

There is no experience with overdose of diclofenac medicated plaster.
Should significant systemic undesirable effects occur following incorrect use or accidental overdose (e.g. in children), the precautions appropriate for poisoning with non-steroidal anti-inflammatory drugs should be taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: topical products for joint and muscular pain; anti-inflammatory preparations, non-steroids for topical use
ATC code: M02AA15

Diclofenac is a non-steroidal anti-inflammatory/analgesic active substance which, via inhibition of prostaglandin synthesis, has been shown to be effective in standard animal models of inflammation. In humans, diclofenac reduces inflammation-related pain, swelling and fever. In addition, diclofenac reversibly inhibits ADP- and collagen-induced platelet aggregation.

5.2 Pharmacokinetic properties

Absorption
Diclofenac is absorbed slowly and incompletely from cutaneous formulations. The plasma concentrations of diclofenac at steady state are characterised by continuous absorption of diclofenac from the plaster, regardless of whether the plaster is applied in the morning or in the evening. Following cutaneous application, diclofenac may be absorbed into a dermal depot, from where it is released slowly into the central compartment. The systemic absorption of topical products is about 2-10 % of that obtained with same dose administered orally.

The observed therapeutic efficacy is mainly explained by therapeutically relevant drug tissue concentrations beneath the site of application. Penetration to the site of action may vary with the extent and nature of the condition and depending on the site of application and action.

Distribution
Plasma protein binding of diclofenac is high at 99 %.

Biotransformation and elimination
Metabolism and elimination are similar after cutaneous and oral use. Following rapid hepatic metabolism (hydroxylation and binding to glucuronic acid), ⅔ of the active substance is eliminated renally and ⅓ by the biliary route.

5.3 Preclinical safety data

Non-clinical data based on conventional studies of safety pharmacology, genotoxicity and carcinogenic potential reveal no special hazards for humans beyond those already outlined in other sections of the Summary of Product Characteristics. In animal studies, chronic toxicity of diclofenac following systemic administration mainly manifested as gastrointestinal lesions and ulcers. In a 2-year toxicity study, rats treated with diclofenac showed a dose-related increase in thrombotic occlusion of the cardiac vessels.

In animal studies on reproductive toxicity, systemically administered diclofenac caused inhibition of ovulation in rabbits and impairment of implantation and early embryonic development in rats. The gestational period and duration of parturition were prolonged by diclofenac. The embryotoxic potential of diclofenac was studied in three animal species (rat, mouse, rabbit). Foetal death and growth retardation occurred at maternotoxic dose levels. Doses below the maternotoxic threshold had no impact on the postnatal development of the offspring.

Diclofenac poses a risk to the aquatic environment (see section 6.6).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Supporting layer
Polyester non-woven fabric

Adhesive layer
Acrylate copolymer
Basic butylated methacrylate copolymer
Polyethylene glycol stearate
Sorbitan oleate
Levomenthol

Liner
One-sided siliconized PET liner

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Diclomel 140 mg medicated plasters are individually enclosed inside PET/Aluminium foil/Transparent polyethylene pouches contained in a carton box.

Each pack contains 2, 5, 7 or 10 medicated plasters.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

This medicinal product poses a risk to the environment (see section 5.3).
Used plasters should be folded in half, with the adhesive side inwards.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel, Co. Tipperary
E91 D768
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/416/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2026

10 DATE OF REVISION OF THE TEXT