Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated plaster contains diclofenac as 140 mg diclofenac sodium.

Excipients with known effect
Each medicated plaster contains 2.90 mg butylated hydroxyanisole (E 320).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster

White 10x14 cm sized self-adhesive plaster made of non-woven fabric on one and paper on other side. Once the protective liner is removed, the adhesive film is translucid bright.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Local symptomatic 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

Posology

Adults and adolescents from 16 years of age
One medicated plaster should be applied to the painful area once daily. The maximum daily dose is 1 medicated plaster a day, 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
Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster 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.

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

Patients with renal or hepatic impairment
In treatment of patients with renal or hepatic impairment see section 4.4.

Paediatric population
The safety and efficacy of Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster in children and adolescents under 16 years of age has not been established (see also section 4.3).

If this medicinal 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 must 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;
- hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs [NSAIDs];
- patients who have previously experienced an asthma attack, urticaria or acute rhinitis when taking acetylsalicylic acid or any other non-steroidal anti-inflammatory drugs (NSAIDs);
- patients with active peptic ulcer;
- on damaged skin, whatever the lesion involved: exudative dermatitis, eczema, infected lesion, burn or wound;
- third trimester of pregnancy;
- 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.

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 preparation is used on large areas of skin and over a prolonged period.
Although the systemic effects are expected to be minimal, the medicated plasters 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.

Butylated hydroxyanisole (E 320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

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. There are no clinical data from the use of Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster during pregnancy. Even if systemic

exposure is lower compared with oral administration, it is not known if the systemic Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster exposure reached after topical administration can be harmful to an embryo/fetus. 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.

Breastfeeding
Diclofenac passes into breast milk in small amounts. However, at therapeutic doses of diclofenac medicated plaster no effects on the breast-fed child are anticipated.
Because of a lack of controlled studies in breast-feeding women, the medicinal product should only be used during breast-feeding under advice from a healthcare professional. Under this circumstance, Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster should not be applied on the breasts of breast-feeding 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

Voltarol Muscle & Joint Pain Relief 140 mg medicated plaster 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 disorders	
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
Rare	Dermatitis bullous (e.g. erythema bullosum),dry skin
Very rare	Photosensitivity reaction
General disorders and administration site conditions	
Common	Application site reactions

Systemic plasma diclofenac levels measured during labelled use of the medicated plasters are very low compared to those obtained after oral intake of diclofenac. The risk of developing systemically induced undesirable effects (like gastric, hepatic and renal disorders, systemic hypersensitivity reactions) 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 muskular pain; Antiinflammatory 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

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. 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.

Mean plateau concentrations are approximately 1 ng/ml. Plasma protein binding of diclofenac is high at 99%. 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. Based on the available non-clinical data, diclofenac is regarded as non-teratogenic. Doses below the maternotoxic threshold had no impact on the postnatal development of the offspring.

Conventional studies on local tolerability reveal no special hazards for humans.

Environmental Risk Assessment (ERA)
Diclofenac poses a risk to the aquatic environment (see section 6.6).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Backing layer:
Polyester non-woven fabric

Adhesive layer:
Polyacrylate dispersion
Tributyl citrate
Butylhydroxyanisole (E 320)

Protective liner:
Mono silicone coated paper

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

The medicated plasters are individually enclosed in sealed sachets made of Paper/PE/Al/EAA.

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

Used plasters should be folded in half, with the adhesive side inwards.

This medicinal product poses a risk to the environment. (See section 5.3).
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA0678/140/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th February 2026

10 DATE OF REVISION OF THE TEXT