

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Sulfate 38.5% w/w Cutaneous Paste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dried magnesium sulfate 38.5% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous paste, white.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For local application to the unbroken skin over such infections as boils and carbuncles.

4.2 Posology and method of administration

Posology

Apply liberally to the affected area with a disposable applicator. Cover with a non-occlusive dressing.

Method of administration

Cutaneous use.

Stir before use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Do not apply to broken skin.

4.4 Special warnings and precautions for use

If there is no improvement, or if there is any aggravation of the condition, consult the doctor or pharmacist.

Prolonged use should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

Magnesium Sulfate 38.5% w/w Cutaneous Paste can be used during pregnancy.

Breast-feeding

Magnesium Sulfate 38.5% w/w Cutaneous Paste should not be applied on the breasts if breast-feeding.

4.7 Effects on ability to drive and use machines

Magnesium Sulfate 38.5% w/w Cutaneous Paste has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None known.

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

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other Dermatologicals, Magnesium sulfate.

ATC code: D11A X05

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol

Glycerol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE jar with LDPE cap.

Pack sizes: 25 g, 50 g and 90 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Foran Healthcare Limited
2 Cherry Orchard Industrial Estate
Dublin 10

8 MARKETING AUTHORISATION NUMBER

PA0484/021/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 1995

Date of last renewal: 21st April 2010

10 DATE OF REVISION OF THE TEXT

September 2016