

1. TRADE NAME OF THE MEDICINAL PRODUCT

Magnesium Sulfate Paste BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Name of ingredient</u>	<u>Quantity</u>
Dried Magnesium Sulfate	47.762g
Phenol	0.497g

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Paste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an adjunct to the management of superficial skin infections, including boils.

4.2 Posology and method of administration

Posology

Adults, elderly and children

Apply to the affected area as required. There is no difference in the quantity required for affected areas or for children, adults or the elderly.

Stir well before use and apply liberally to the affected area.

Cover with a dressing.

Method of Administration

For topical application

4.3 Contraindications

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

4.4 Special warnings and precautions for use

For external use only.

Do not use repeatedly.

4.5 Interactions with other Medicaments and other forms of Interaction

No significant clinical interactions known.

4.6 Fertility, pregnancy and lactation

As with all medicines it may be used during this period if the benefits outweigh the risks.

4.7 Effects on Ability to Drive and Use Machines

Not applicable.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Should accidental ingestion occur, treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other Dermatologicals, Magnesium Sulfate
ATC code: D11A X05

Topical application of the ingredients of the paste help to draw infected wounds and reduce inflammation.

5.2. Pharmacokinetic Properties

Not applicable.

5.3. Preclinical Safety Data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of ingredient	Quantity
Glycerol	51 .7g

6.2. Incompatibilities

None known.

6.3. Shelf Life

3 years.

6.4. Special Precautions for Storage

Store below 25°C.

6.5. Nature and Contents of Container

Polypropylene tub and lid with tie sealed tamper evident top containing 25g or 50g.

HDPE tub and lid with tie sealed tamper evident top containing 25g or 50g.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

KL Pharmaceutical Limited
21 Macadam Place
South Newmoor Industrial Estate
Irvine
Ayrshire
KA11 4HP

8. Marketing Authorisation Number

PL 03436/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/05/2008

10 DATE OF REVISION OF THE TEXT

10/04/2017