

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

KAOLIN POULTICE BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Name of Ingredient</u>	<u>Quantity (per kg)</u>
Heavy Kaolin	527.0g
Thymol	0.5g
Boric Acid	45.0g
Peppermint Oil	0.5g
Methyl Salicylate	2.0ml

All ingredients are of BP quality

3 PHARMACEUTICAL FORM

Poultice.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Reduces inflammation and alleviates pain.

4.2 Posology and method of administration

Method of administration External application to the affected area.

Posology External poultice applied on a foil backing or directly.

Adults, elderly and children To be used on adults only.

4.3 Contraindications

Known hypersensitivity to salicylates or any other ingredients.

4.4 Special warnings and precautions for use

To be applied on unbroken skin of adults only.

Test heat of poultice before use.

For external use only.

Keep out of the reach of children.

Close container when not in use.

For use on adults only (including the elderly).

Not to be used on infants and children.

Not to be used on broken skin

4.5 Interaction with other medicinal products and other forms of interaction

No significant clinical interactions known.

4.6 Fertility, pregnancy and lactation

As with all medicines, avoid in pregnancy and breast feeding, unless advised by a medical practitioner.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Rarely hypersensitivity reactions can occur.

4.9 Overdose

Should accidental ingestion occur, treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Topical application of the ingredients of the poultice help to alleviate pain and reduce inflammation.

5.2 Pharmacokinetic properties

The amount of Salicylate included in the product is small and therefore unlikely to cause any significant hazard.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Polypropylene tub containing 200, 500 or 1000g.
Laminated foil pouch containing 100g.

6.6 Special precautions for disposal

Pouches

- 1 Heat the poultice in boiling water for not more than 40 seconds.
- 2 Remove from the boiling water.
- 3 Place pouch on a flat surface and cut around edges with scissors.
- 4 Remove clear cover.
- 5 Test heat before use.
- 6 Apply to the affected area and bandage in place.

Jars

- 1 Loosen lid of jar. Heat in hot water until contents are hot.
- 2 Do not bring jar into contact with direct heat by any other means.
- 3 Stir thoroughly.
- 4 Spread thickly on lint or a suitable alternative.
- 5 Test heat before use.
- 6 Apply to affected area. Bandage lightly.
- 7 Leave in place for 12 to 24 hours as directed by medical advice.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 03436/0001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

02/11/2005

10 DATE OF REVISION OF THE TEXT

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