SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kaolin Poultice B.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Heavy Kaolin	52.70 g
Thymol	0.05 g
Boric Acid	4.50 g
Peppermint Oil	0.05 ml
Methyl Salicylate	0.20 ml
Glycerol	42.50 g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Poultice Thick dense grey paste.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

As an aid in the reduction of inflammation and to alleviate pain in horses.

4.3 Contraindications

Do not use in known cases of hypersensitivity to kaolin or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use as directed, or as instructed by a veterinarian. If signs of disease persist or appear, consult a veterinary surgeon. Ensure that the bandage is not applied too tightly so as to constrict circulation. For external use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product may cause skin and eye irritation. Avoid contact with skin and eyes. Wear impervious gloves when using the product.

In the event of contact with the eyes, rinse immediately with plenty of clean water for several minutes. Seek medical attention if irritation persists.

In the event of contact with the skin, rinse immediately with plenty of clean water. Seek medical attention if irritation persists.

Wash hands and exposed skin thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

Rarely hypersensitivity reactions can occur.

4.7 Use during pregnancy, lactation or lay

Avoid use in pregnancy and lactation, use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No significant clinical interactions known.

4.9 Amounts to be administered and administration route

<u>Hot</u>

Take the required amount of Kaolin Poultice BP from the tub and put into a container suitable for heating. Place the container in hot water making sure that no water can get in. Stir thoroughly, making sure that the material is heated evenly, then spread thickly onto lint or any other suitable material. Test the temperature of the poultice before applying to the affected area. Apply to the affected area and bandage tightly. The poultice may be left on for 12 - 24 hours (according to veterinary advice) and then washed off.

<u>Natural</u>

Kaolin Poultice BP may be used straight from the tub. No heating or cooling is required. Take the required amount of material from the tub and spread thickly onto lint or any other suitable material. Apply to the affected area and bandage tightly. Wash off to remove.

<u>Cold</u>

Prepare as above then place in a fridge to chill to the required temperature. Apply to the affected area and bandage tightly. Wash off to remove.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Should accidental ingestion occur, treat symptomatically.

4.11 Withdrawal period(s)

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Poultice ATCvet code: QD09

5.1 Pharmacodynamic properties

Kaolin Poultice BP possesses emollient properties. It provides heat and moisture locally to relieve pain and draw pus, if present, from a wound. It also exerts an osmotic effect, collecting fluid and toxic products at the site of application. A rubifacient or counter – irritant action may be obtained.

5.2 Pharmacokinetic particulars

No information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 30 °C Store in the original container Keep the container tightly closed

6.5 Nature and composition of immediate packaging

Polypropylene tub and lid containing 1kg. High density polyethylene tub and lid containing 4kg.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 03436/4001

9. DATE OF FIRST AUTHORISATION

30 June 1992

10. DATE OF REVISION OF THE TEXT

March 2017

PROHIBITION OF SALE, SUPPLY AND/OR USE

None

D. Austin-

Approved: 03 March 2017