SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animalintex Hoof Treatment Poultice

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pad contains:	Boric Acid	0.39 g

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Poultice
A non-sterile dressing

4. CLINICAL PARTICULARS

4.1 Target species

Horse

4.2 Indications for use, specifying the target species

Horse as applicable
The poultice may be used as follows:-
HOT
For infected or dirty wounds, hoof punctures, removing thorns, abscesses, coronary band abscesses, Quittor-in-the-hoof, thrush, corns (infected or sterile), bruised sole, seedy toe, laminitis, sandcrack and 24 hours after an injury to provide warmth for bruises, contusions.

COLD
For bruises, contusions, laminitis and first 24 hours of any inflamed injury with heat and/ or swelling, followed by hot application for warmth.

AS A DRY DRESSING
To stop bleeding, protect from further infection, treat wounds and promote faster healing.

4.3 Contraindications

Do not use with medical preparations except on the advice of a veterinary surgeon.
Animalintex Hoof Treatment should not be used on horses known to be sensitised to Tragacanth.

4.4 Special warnings for each target species

The over-use of hot, wet dressings to an open wound or abscess may encourage the development of excessive granulation tissue (proud flesh).

4.5 Special precautions for use

i. Special precautions for use in animals

Ensure the dressing is not applied too hot, i.e. by testing on the back of the hand.
Ensure that the bandage is not applied too tightly.
If a skin reaction occurs when adhesive dressings are used to hold the product in place, their use should be discontinued. Skin reaction is characterised by soreness and serum exudate at the site.
Consult a veterinary surgeon before applying to infected wounds.
For external use only

ii. Special precautions for the person administering the veterinary medicinal product to animals

Wash hands after application of a poultice

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Minor reactions in horses to the Tragacanth ingredient have been reported at a very low frequency. These reported minor reactions do not exceed 2 per million units.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation provided the precautions described in the leaflet are observed, i.e.

- Change Animalintex Hoof Treatment at least once every twelve hours.
- Do not apply too hot, i.e. it should feel comfortable on thr back of your hand.
- Ensure the poultice is applied with the plastic waterproof backing away from the animal.

- Do not bandage too tightly.
- If the skin is broken, anti-tetanus cover is required.
- If adhesive dressings are used on animals, they should be discontinued if a skin reaction occurs. This is characterised by soreness, redness and serum exudate at the site.

If in doubt, consult a veterinary surgeon

4.8 Interaction with other medicinal products and other forms of interaction

Should not be used with other topical treatments except with veterinary advice. The occlusive conditions which occur under a hot wet pad can potentiate a topical treatment, e.g. wound powder and produce an adverse reaction

4.9 Amount(s) to be administered and administration route

The area to be poulticed should be washed initially by clean water or by boiled, cooled water. If the skin is broken or infected, boiled cooled water and a saline solution should be used. Place the dressing in a shallow tray of boiled water cooled to 38°C. (100°F.). Once it is saturated, remove the dressing and gently squeeze out excess water. Place on the affected area with the polythene facing outward. Care should be taken to ensure the temperature does not exceed 40°C. i.e.: bearable on the back of the hand.

For ponies, poultice needs to be cut to an appropriate size.

Cold Poultice Dressing
After soaking the dressing in cooled, boiled water, apply the cool dressing to the affected area.

Dry Dressing
Simply apply the dressing directly and bandage

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

The risk of overdosing with Boric Acid is absent. However, poultices can be left on too long and can lead to skin maceration. Follow instructions to change the dressing every 12 hours.

4.11 Withdrawal period(s)

HORSES : MEAT – 7 days from the removal of the last dressing

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Gum Tragacanth Ph. Eur.
Tragacanth on its own has no particular pharmacological properties but in the presence of warm/hot water and boric acid, it acts as a “drawing” agent. Since it is sparingly soluble in water, but is “gummy”, it holds the boric acid powder within the spaces of the cotton fibers in the pad. Once the skin is softened in wet conditions, it promotes the drawing of pus from boils and abscesses and eases the removal of thorns and foreign matter from wounds. Occasional hypersensitivity to Tragacanth may be experienced.

Boric Acid Ph. Eur.
Boric Acid is a weak acid; a 3.33% solution in water having a pH of 3.8 to 4.8. It has mild properties both antifungal and anti-bacterial. A 1.9% aqueous solution is iso-tonic. It is soluble in water : 5% at 22°C and 27.7% at 100°C. However, since a pad absorbs x8.3 its weight in water, the normal concentration of Boric acid in the solution is 0.56%. At this concentration the solution would have no osmotic effect.

5.2 Pharmacokinetic properties

Studies conducted on horses show that any Boric acid absorbed through broken skin into the blood is only moderately above blood levels following ingestion from pastures and hay. Any excess is rapidly excreted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tragacanth

6.2 Major incompatibilities

Do not use the product with other topical medicinal products

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a dry place

6.5 Nature and composition of immediate packaging

Three 8.73 g poultice dressings packed singularly in a white opaque 30 micron low density polyethylene, heat sealed bag with blue/green/black label

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

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

Robinson Healthcare Ltd
Lawn Road Industrial Estate
Carlton-in-Lindrick
Worksop
Nottinghamshire
S81 9LB

8. MARKETING AUTHORISATION NUMBER

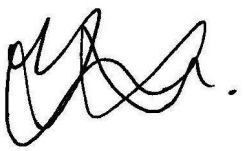
Vm 19434/4000

9. DATE OF FIRST AUTHORISATION

17 July 1996

10. DATE OF REVISION OF THE TEXT

January 2020



Approved: 22 January 2020