SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Golden Hoof 100%w/w Powder for cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	Quantity
Zinc Sulphate Hexahydrate $ZnSO_4.6H_2O$	min 100% w/w

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for cutaneous solution.
Small monoclinic or rhombic crystals for dissolution in water and subsequent topical application.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

For the control and healing of footrot and footscald in sheep.

4.3 Contraindications

None.

4.4 Special warnings:

Can be dangerous if taken internally in quantity. Although poorly absorbed from the gut, zinc can cause corrosive toxicity in the G-I tract.

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.

Drinking water should be made available in order to prevent animals from drinking the solution in cases of extreme thirst.

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

Wash hands and exposed skin before meals and after work.
Wash splashes from the eyes immediately with clean water.
Wear Wellington boots and rubber gloves when handling the solid or solution.
Prevent access to the bath by children and animals when not being used.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No adverse effects from use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product should be mixed with water to provide a 10% (w/v) solution for topical application as a footbath (1kg powder / 10 litres in water). The volume of water required to provide sufficient depth to allow complete immersion of the feet should be determined and the corresponding quantity of the product used.

All animals in a group should be treated.

Badly infected feet should be sparingly and carefully pared to expose infected tissue before footbathing. Paring equipment should be disinfected between each animal being treated.

For maintenance treatment at times of high risk and for the treatment of footscald sheep should stand in the footbath solution for a minimum of 2 minutes.

For the treatment of footrot separate out infected animals and stand in the solution for up to 30 minutes.

Animals should be allowed sufficient time (minimum of 15 minutes) for drying, on concrete or grating, before returning to grass (preferably rested from sheep for at least two weeks)

Repeat treatment at 7 day intervals to bring the infection under control (minimum of three weeks) and thereafter at 1 – 2 weeks intervals during period when infection is likely to spread.

If treatment with the product should fail, then it is advisable to reconsider the cause of the condition, especially if Contagious Ovine Digital Dermatitis could be a complicating factor.

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

Zinc sulphate is poorly absorbed through the skin. Therefore providing drinking water is provided prior to foot bathing to prevent oral intake of the prepared dip, overdose is not applicable.

4.11 Withdrawal periods

Meat: 0 days
Milk: 0 hours

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc sulphate has antiseptic properties without the irritancy of some other metallic compounds. It is also believed to harden the hoof.

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5.2 Pharmacokinetic properties

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nil.

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

Store in a dry place.
Close the bag securely after use.
Keep in a tightly closed original container.

6.5 Nature and composition of immediate packaging

Low density polyethylene white sacks or low density polyethylene white heat sealed sacks within a white plastic bucket with lid containing 10kg or 20kg. Not all pack sizes may be marketed.

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

Do not contaminate water including ponds, ditches, ground and surface waters. Should it be necessary to dispose of unused solution, contact your nearest Environment Agency for advice.

7. MARKETING AUTHORISATION HOLDER

Shep-Fair Products Ltd
Unit 4
Wonastow Industrial Estate West
Monmouth
NP25 5JA

8. MARKETING AUTHORISATION NUMBER

Vm 06077/4000

9. DATE OF FIRST AUTHORISATION

29th April 1985

10. DATE OF REVISION OF THE TEXT

June 2016

14 June 2016