

Summary of Product Characteristics

1 Name of the veterinary medicinal product

Zincoped.
100% w/w cutaneous powder for solution.

2. Qualitative and Quantitative composition

Active substance:

Zinc Sulphate as Heptahydrate 100%w/w

For a full list of excipients, see section 6.1

3. Pharmaceutical form.

Cutaneous powder for solution.

4. Clinical particulars.

4.1 Target species;

Sheep

4.2 Indications for use, specifying the target species;

For the control of foot rot in sheep

4.3 Contra indication;

None

4.4 Special warnings for each target species;

Good footbathing practice should be followed.
For external use only.

4.5 Special precautions for use;

i) Special precautions for use in animals.

Foot rot is highly contagious, treated sheep should not be returned to infected pasture for at least a week if this can possibly be avoided.

Ensure that all animals are well watered before entering the bath, observe at all times and prevent them from drinking the bath.

The water must be deep enough to completely cover the feet.

Badly affected feet should be trimmed to aid treatment. In severe cases repeat the treatment at weekly intervals.

ii) Special precautions to be taken by the person administering the 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 if used according to the label instructions.

4.7 Use during pregnancy, lactation or lay;

Suitable for the treatment of pregnant and lactating sheep.

4.8 Interaction with other medicinal products and other forms of interaction;

Interaction with medicinal products – None reported.

Other - Do not mix the product with any other product.

4.9 Amounts to be administered and administration route;

Prepare a 10% solution of Zincoped in water as a footbath (1lb per gallon, 1Kg per 10 litres of water). Top up the bath as necessary with the same strength solution.

Sheep with muddy feet should be put through a wash bath first.

Sheep should be allowed to stand in the solution for at least 2 minutes and then be allowed sufficient time for drying before returning to grass.

The effectiveness of the bath will be reduced if contaminated with mud or dung.

All the animals in a group should be treated. Treatment should be repeated in 2 weeks if infection is likely to re-appear.

The footbath should be emptied and cleaned after each treatment period.

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

Not likely

4.11 Withdrawal period for the various foodstuffs, including those for which the withdrawal period is zero;

Sheep – Meat – Zero days

Milk – Zero hours

5. Pharmacological Properties.

5.1 Pharmacodynamic properties;

ATCvet code QD51

The substance has anti-bacterial and anti-fungal activities. It is less irritant than other metallic salts used for footbathing. Zinc sulphate is also less toxic to sheep than Copper Sulphate which has been used in the past.

5.2 Pharmacokinetic properties;

Inorganic salt are not likely to be absorbed through the foot

6 Pharmaceutical particulars

6.1 List of excipients;

None

6.2 Incompatibilities

None known

6.2 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.

Store in tightly closed original container.

The bath should be discarded when it becomes too fouled with droppings etc., cleaned and refilled with a fresh solution.

6.5 Nature and composition of immediate packaging.

Pack sizes of 12.5Kg and 20Kg in a polypropylene bucket with re-sealable polypropylene push fit lid.

Not all pack sizes may be marketed.

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

Do not contaminate water including ponds, ditches, ground and surface waters. It is an offence to permit any poisonous, noxious or polluting matter to enter any river, stream or watercourse. Do not use soakaways as a means of disposal.

To dispose of used Zincoped solution an authorisation under the Groundwater Regulations 1998 is required. To apply for an authorisation contact the Environment Agency or the Scottish Environment Protection Agency (SEPA) or the Environment and Heritage Service of the Department of Environment for Northern Ireland (EHS/DENI). Alternatively spent Zincoped solution should be disposed of by a licensed waste disposal contractor.

If you have an area of land authorised for the disposal of Zincoped solution, you should apply no more than 600 litres of spent bath per hectare (50 gallons/acre). Dilution of 1 part of Zincoped solution by 30 parts or more of water or slurry may be necessary to achieve this application rate.

Concentrate should be disposed of by a specialist waste disposal contractor.

Containers should be washed out and the rinsings added to the footbath.
Puncture the container to prevent re-use and dispose of by normal means.
Consult the following for further advice on the safe disposal of spent footbath
liquors and their containers:

Code of good agricultural practice for the protection of water: Available
free of charge from DEFRA Publications, London SW1A 2XX.

Code of good agricultural practice for the protection of soil: Available free
of charge from DEFRA Publications, London SW1A 2XX.

The Code of Good Practice for The Prevention Of Environmental Pollution
From Agricultural Activity: Available from SOAFD, Edinburgh, EH14 1TW.

7. Marketing Authorisation holder.

Battle, Hayward and Bower Ltd
Crofton Drive,
Lincoln.
LN3 4NP

8. Marketing Authorisation Number

Vm 00676/4098

**9. Date of the first authorisation or date of last renewal of the
authorisation**

26th January 1991

10. Date of revision of the text

21 August 2008