PROVITA HOOFSURE ENDURANCE XL- formic acid solution, concentrate Provita Eurotech Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Provita Hoofsure Endurance XL

Hoofsure Endurance is a scientifically proven proprietary blend of organic acids, essential oils and wetting agents specifically designed and formulated to both clean and care for hooves. It is safe, non-toxic, biodegradable and does not contain copper, formaldehyde or antibiotics.

Hoofsure Endurance is intended for use as part of a hoof maintenance program in conjunction with your veterinarian. Hoof health is dependent on good nutrition, hygiene, management and herd health care. Footbathing is a control measure and not a treatment. To optimize hoof health, a treat and control protocol is recommended. Lame cows should be identified, footbathed regularly and treated with an appropriate product such as Provita Konquest gel and Provita Combat spray.

Ingredients

Organic Acids (Acetic and Formic), Water, Ethanol, Alkoxylated Cetyl Alcohol, Laureth-4, Tea-tree Oil, E124, E133

Disposal

Hoofsure Endurance is environmentally friendly. After use, spent footbath can be disposed of by landfill or flushing to a slurry lagoon in accordance with local regulations.

Precautions

Do not use in galvanised footbaths.

Care must be taken when handling undiluted product.

Wear suitable protective clothing and eye protection.

Do not breathe vapour.

Contains Formic Acid.

Causes burns.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Keep out of reach of children.

See Health and Safety Data Sheet.

Directions for Use

DAIRY CATTLE For footbath use: For optimum results footbath at every milking, every day. Mix Hoofsure Endurance 1:100 (equivalent to a 1% solution - e.g. half gallon of Hoofsure Endurance with 50 gal clean water in a 50 gal footbath). When required, a 2% or above dilution rate may be used. Place footbath in return alley, not in parlor. Wash dirt and manure off feet prior to walking through the footbath. Ideally, use a pre-wash bath.

Number of cow passes before filling fresh footbath (approximate):

Footbath Capacity	Number of Cow Passes*
25 gals	up to 250
50 gals	up to 500
100 gals	up to 1000

^{*} Ensure footbath solution is at 5" depth or above at all times. Check depth of solution every 200 cows and top up, as necessary, using a top up solution (mix ½ gallon of Hoofsure Endurance with 5 gallons of water and add to the footbath. Use of heavily soiled footbaths can become a source of infection or re-infection.

For topical application: After inspection or trimming, administer a 25% solution of Hoofsure Endurance (i.e. 4 oz Provita Hoofsure Endurance mixed with 20 oz of clean water). Using a sprayer, apply to the hoof once per day for up to 3 weeks.

BEEF CATTLE For footbath use: Footbath every 4-6 weeks. Mix Hoofsure Endurance 5:100 (equivalent to a 5% solution - e.g. 5 gallons of Hoofsure Endurance with 100 gal clean water in a 100 gal footbath). Wash dirt and manure off feet prior to walking through the footbath. A 100 gal footbath can have 1000 cow passes before needing filled fresh.

*Ensure footbath solution is at 5" depth or above at all times. Check depth of solution every 200 cows and top up, as necessary, using a top up solution (mix ½ gallon of Hoofsure Endurance with 5 gallons of water and add to the footbath. Use of heavily soiled footbaths can become a source of infection or reinfection.

For topical application: After inspection or trimming, administer a 25% solution of Hoofsure Endurance (i.e. 4 oz Provita Hoofsure Endurance mixed with 20 oz of clean water). Using a sprayer, apply to the hoof.

SHEEP For footbath use: Footbath every 2-4 weeks. Mix Hoofsure Endurance 1:100 (equivalent to a 1% solution - e.g. half gallon of Hoofsure Endurance with 50 gal clean water in a 50 gal footbath). When required, a 2% dilution rate may be used. Walk sheep through footbath 3 times or allow sheep to stand in the solution for a short period. A 50 gal footbath can have up to 1000 sheep passes before needing filled fresh.

Number of sheep passes before filling fresh footbath (approximate):

Footbath Capacity	Number of Sheep Passes*
25 gal	up to 500
50 gal	up to 1000

^{*} Ensure footbath solution is at 3" depth or above at all times. Check depth of solution every 100 sheep and top up, as necessary, using a top up solution (mix ½ gallon of Hoofsure Endurance with 5 gallons of water and add to the footbath).

For topical application: After inspection or trimming, administer a 25% solution of Hoofsure Endurance (i.e. 4 oz Provita Hoofsure Endurance mixed with 20 oz of clean water). Using sprayer, apply to the hoof.

1.25gal (4.75 Litres)

Provita Eurotech Limited,

21 Bankmore Road, Omagh, Co. Tyrone, Northern Ireland, BT79 0EU **Provita Animal Health LLC** 4500 140TH Avenue North, Suite 101 Clearwater, FL 33762 Tel: + (1) 727 431 9511 Email: info@provita-animalhealth.com

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PRINCIPAL DISPLAY PANEL - 992 Litre Drum Label

Provita

Animal Health Naturally

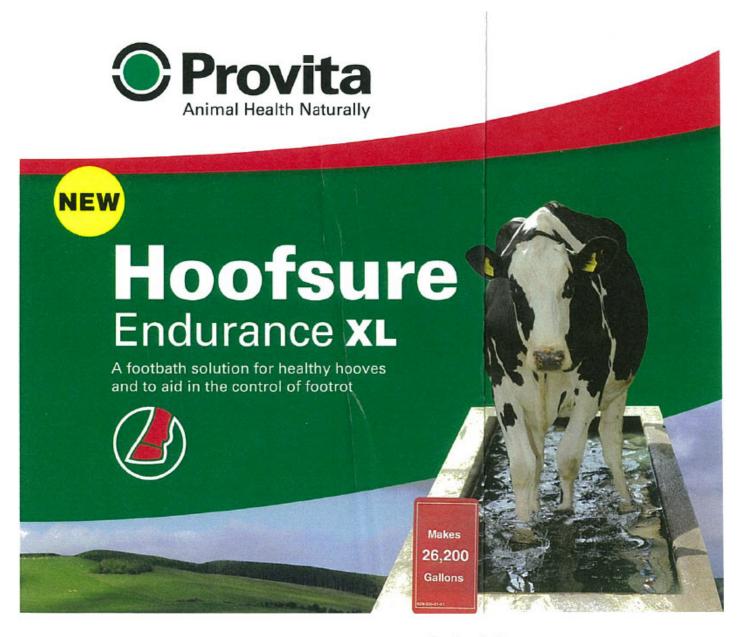
NEW

Hoofsure

Endurance XL

A footbath solution for healthy hooves and to aid in the control of footrot

Makes 26,200 Gallons



Hoofsure Endurance is a scientifically proven proprietary blend of organic acids, essential oils and wetting agents specifically designed and formulated to both clean and care for hooves. It does not contain copper, formaldehyde or antibiotics. Hoofsure Endurance is intended for use as part of a hoof maintenance program in conjunction with your veterinarian. Hoof health is dependent on good nutrition, hygiene, management and herd health care. Footbathing is a control measure and not a treatment. To optimize hoof health, a treat and control protocol is recommended. Lame cows should be identified, footbathed regularly and treated with an appropriate product such as Provita Konquest gel and Provita Combat spray.

Ingredients: Organic Acids (Acatic and Formic), Water, Ethanol, Alkoxylated Cetyl Alcohol, Laureth-4, Tea-tree Oil, E124, E133

Disposal: Hoofsure Endurance is not subject to bioaccumulation. After use, spent footbath can be disposed of by landfill or flushing to a slurry lagoon in accordance with local regulations.

Danger



Flammable liquid and vapour. Harmful if swellowed. Causes severe skin burns and eye damage. Keep away from heat/ sparks/open flames/hot surfaces — No smoking. Do not breathe dust / fume / gas / mist / vapours / spray.



Wear protective gloves/ protective clothing/eye protection/face protection.



IF SWALLOWED: Rinse mouth. Do NOT induce vorniting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/ shower. IF INHALED: Remove victim to fresh sir and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do, continue rinsing. If

Directions for Use

Dairy Cattle

For footbath use: For optimum results footbath at every milking, every day. Mix Hoofsure Endurance 1:100 (equivalent to a 1% solution - e.g. half gallon of Hoofsure Endurance with 50 gal clean water in a 50 gal footbath). When required, a 2% or above dilution rate may be used. Place footbath in return alley, not in parlor. Wash dirt and manure off feet prior to welking through the footbath. Ideally, use a pre-wash bath.

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100 gals	up to 1000

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For topical application: After inspection or trimming, administer a 25% solution of Hoofsure Endurance (i.e. 4 oz Provita Hoofsure Endurance mixed with 20 oz of clean water). Using a sprayer, apply to the hoof once per day for up to 3 weeks.

Beef cattle

For footbath use: Footbath every 4-5 weeks. Mix Hoofsure Endurance 5:100 (equivalent to a 5% solution - e.g. 5 gallons of Hoofsure Endurance with 100 gal clean water in a 100 gal footbath). Wash dirt and manure off feet prior to walking through the footbath. A 100 gal footbath can have: 1000 cow passes before needing filled fresh.

*Ensure footbath solution is at 5" depth or above at all times. Check depth of solution every 200 cows and top up, as necessary, using a top up solution (mix ½ gallon of Hoofsure Endurance with 5 gallons of water and add to the footbath. Use of heavily soiled footbaths can become a source of infection or re-infection.

For topical application: After inspection or trimming, administer a 25% solution of Hoofsure Endurance (i.e. 4 oz Provita Hoofsure Endurance mixed



symptoms persist, immediately call a POISON CENTER or doctor/physician. In case of fire: Use water, carbon dioxide (CO2), foam, dry powder for extinction. Store in a well-ventilated place. Keep cool. Keep out of reach of children. For animal use only. Do not use in galvanised footbaths.



Batch No: 26268
Best Before: Jun 2020
262gal
(992 Litres)

Provita Eurotech Limited, 21 Bankmore Road, Ornagh, Co. Tyrone, Northern Ireland, BT79 0EU

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with 20 oz of clean water). Using a sprayer, apply to the hoof.

Sheep

For footbath use: Footbath every 2-4 weeks. Mix Hoofsure Endurance 1:100 (equivalent to a 1% solution - e.g. half gallon of Hoofsure Endurance with 50 gal clean water in a 50 gal footbath). When required, a 2% dilution rate may be used. Walk sheep through footbath 3 times or allow sheep to stand in the solution for a short period. A 50 gal footbath can have up to 1000 sheep passes before needing filled fresh.

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formic acid solution, concentrate

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:16371-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FORMIC ACID (UNII: 0 YIW783RG1) (FORMIC ACID - UNII:0 YIW783RG1)	FORMIC ACID	608 g in 1 L	

Inactive Ingredients		
Ingredient Name	Strength	
CETYL ALCOHOL (UNII: 936JST6JCN)		
LAURETH-4 (UNII: 6HQ855798J)		

Product Characteristics		
Color	BLUE	Score
Shape		Size
Flavor		Imprint Code
Contains		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16371-106-01	4.75 L in 1 DRUM		
2	NDC:16371-106-02	19 L in 1 DRUM		
3	NDC:16371-106-03	57 L in 1 DRUM		
4	NDC:16371-106-04	114 L in 1 DRUM		
5	NDC:16371-106-05	209 L in 1 DRUM		
6	NDC:16371-106-07	992 L in 1 DRUM		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/04/2004	

Labeler - Provita Eurotech Ltd (238318232)

Establishment			
Name	Address	ID/FEI	Business Operations
Provita Eurotech Ltd		220688192	MANUFACTURE, PACK, LABEL, ANALYSIS, API MANUFACTURE

Revised: 10/2018 Provita Eurotech Ltd