

Dechra Veterinary Products Limited

(A business unit of Dechra Pharmaceuticals PLC)
Sansaw Business Park
Hadnall, Shrewsbury
Shropshire SY4 4AS

Tel: 01939 211200 Fax: 01939 211201

Email: info.uk@dechra.com

Website: www.dechra.com



MYCOZOLE® 10 MG/ML SPRAY FOR TOPICAL ADMINISTRATION

Small Animal Exemption Scheme (SAES) product
Qualitative and quantitative composition 1 ml spray contains: Active substance: Miconazole nitrate 10 mg

Pharmaceutical form Spray for topical administration.

Clinical particulars

Target species: Rabbits, guinea pigs, small rodents, birds, reptiles.

Indications for use: Topical antifungal spray for the prevention and treatment of fungal and bacterial infections of the skin in rabbits, guinea pigs, small rodents, birds and reptiles.

The active ingredient miconazole nitrate is effective against common fungal infections of the skin such as *Candida* spp., *Malassezia pachydermatis* and *Dermatophytosis* (ringworm) caused by *Microsporum* spp. or *Trichophyton* spp. Mycozole will also treat bacterial infections of the skin caused by *Streptococcus* spp., *Pseudomonas* spp. and others susceptible to imidazole type drugs.

Contraindications: For external use only. May irritate the eyes. Do not apply to or around the eyes.

Do not use in conjunction with any other medicine.

Do not use in pregnant or lactating animals.

Do not use in animals less than 100 g body weight.

Special precautions for use: If signs of disease persist beyond 7 days, or reappear, then advice must be sought from a veterinary surgeon.

Special precautions to be taken by the person administering the product to animals: Ringworm is infectious to humans so it is advisable to wear gloves while handling and treating animals in which ringworm has been diagnosed or is suspected.

Wash hands with soap and water after application.

Do not drink or smoke while applying this product.

Adverse reactions: As with many topically applied products, local irritation may occur. Should such a reaction occur, discontinue use and consult a veterinary surgeon.

If you notice any serious effects or other effects not mentioned in this data sheet, please inform your veterinary surgeon.

Amounts to be administered and administration route: Topical antifungal spray.

Dose rate: 1 ml/kg body weight twice daily.

Species	Body weight	Amount to use	Frequency of use
All target species	100-200 g	0.2 ml (1 pump)	Twice daily
	200-400 g	0.4 ml (2 pumps)	
	400-600 g	0.6 ml (3 pumps)	
	600-800 g	0.8 ml (4 pumps)	
	800 g-1 kg	1 ml (5 pumps)	
	Over 1 kg	0.2 ml (1 pump) per 200 g	

Weigh animal carefully before administration to accurately assess the appropriate dose.

Remove drinking water before use and replace with fresh water after application.

Treat all animals in a group at the same time.

Spray twice daily at a distance of 5 cm to 10 cm from the animal, ensuring that the product reaches the skin. In mammals and birds this will require lifting the fur or feathers to expose the skin surface.

Continue application at this rate until the skin condition improves, but not longer than 7 days. If signs of disease persist beyond 7 days or reappear,

then advice must be sought from a veterinary surgeon.

Withdrawal period: For pet animals only. Do not use in animals intended for human consumption. Do not eat the eggs of treated birds.

Pharmaceutical particulars

Special precautions for storage: Keep out of the sight and reach of children. Do not store above 25°C. Do not freeze. Protect from direct sunlight.

No in-use shelf life studies have been undertaken on this product.

Immediate packaging: High density polypropylene (HDPE) container containing 50 ml with pump aerosol.

Disposal: Dispose of waste materials in accordance with local requirements.

Legal category SAES

Further information *Manufacturer's authorisation number:* SAM 0011

For animal treatment only.

For any information about this veterinary medicinal product, please contact the distributor.

Date of last review: September 2013

GTIN (Global Trade Item No)

Mycozole 10 mg/ml Spray for Topical Administration
50 ml: 05060019580707

Requested by: lynne.easton@dechra.com

Creation date: 9/10/2013 14:28:37 (UK)

Approved datasheets found: 1

Approved for book but not on website: 0

Datasheets marked as draft (ignored): 0



Product	Company	Cattle Milk	Cattle Meat	Sheep Meat	Pigs Meat	Poultry Meat	Poultry Eggs	Fish Meat	Notes
Mycazole 10 mg/ml Spray for Topical Administration	Dechra Veterinary Products Limited	-	-	-	-	-	-	-	For pet animals only. Do not use in animals intended for human consumption. Do not eat the eggs of treated birds.

Directory of participants

Dechra Veterinary Products page
Limited
(A business unit of Dechra
Pharmaceuticals PLC)
Sansaw Business Park
Hadnall, Shrewsbury
Shropshire SY4 4AS

Tel: 01939 211200
Fax: 01939 211201
email: info.uk@dechra.com
www.dechra.com **000**

List of Products by Therapeutic Indication

PHARMACEUTICALS

Antimicrobials

Topical preparations

Skin

Mycozole 10 mg/ml Spray for Topical
Administration 1

List of Products by Species

Please note that a species in brackets after a product name may not necessarily be a part of that product name but is intended to make the index easier to use.

Ornamental birds

Mycozole 10 mg/ml Spray for Topical Administration 1

Pigeons

Mycozole 10 mg/ml Spray for Topical Administration 1

Rabbits

Mycozole 10 mg/ml Spray for Topical Administration 1

Reptiles

Mycozole 10 mg/ml Spray for Topical Administration 1

Small mammals

Mycozole 10 mg/ml Spray for Topical Administration 1



List of Products by Active Ingredients

This index of non-proprietary names (active ingredients) is provided to enable users of the Compendium to identify the brand names of relevant products when only the non-proprietary names are known.

It should be noted that although different products may contain the same active ingredient this does not imply that they are equivalent in regard to bioavailability or therapeutic activity.

Some products contain a number of ingredients and it has not been possible in every instance to identify such products by a reference in this index to each ingredient.

Key

Non-proprietary name in bold type. Proprietary name in ordinary type.

Miconazole Nitrate

Mycozole 10 mg/ml Spray for Topical
Administration 1

Alphabetical Index of Products

Mycozole 10 mg/ml Spray for
Topical Administration 1

ALPHABETICAL