For Veterinary Use Only

Fungusole®

Concentrate Emulsion

Veterinary

COMPOSITION

Fungusole 10% EC is a yellow-dark yellow colored clear solution containing 100 mg of enilconazole per each ml.

PHARMACOLOGIC PROPERTIES

Enilconazole is an antifungal drug of azole group. Mechanism of action is based on inhibition of chromosomal p450 taking place in ergosterol synthesis. Thus, availability of ergosterol required for function of normal fungal cell membrane and accumulation of methylsterols can be decreased. Ergosterol is a necessary compound for normal fungal plasma membranes. It regulates the permeability of membranes and activity of membrane enzymes.

It is effective on Trichophyton verrucosum, Trichophyton mentagrophytes, Trichophyton equinum, Microsporum canis, Microsporum gypseum as well as Aspergillus sp.

Enilconazole is administered topically as it has a low solubility and limited intestinal absorption. When administered on skin, it reaches to peak plasma levels (48.5 mg/ml) within 1 hour and then rapidly decreases. It does not accumulate in fatty tissue. A substantial part of the administered dose is excreted on the first day, and the remaining part is excreted in urine and faeces on the second day.

Toxicity:

It has a low acute toxicity and high safety margin even while inhaled or in intraperitoneal administration. Oral LD50 value is 390.7 mg/kg in male rats, and 620.5 mg/kg in female rats. Acute dermal LD50 value is 4200 mg/kg in male rats and 4880 mg/kg in female rats. Irritation and sensitivity-causing potential of enilconazole was found low in local tolerance studies conducted with rabbits.

AREA OF USE/INDICATIONS

It is used in treatment of dermatomycosis and dermatophytosis infections caused by Trichophyton verrucosum, Trichophyton mentagrophytes, Trichophyton equinum, Microsporum canis, and Microsporum gypseum in cattle-horses and dogs.

USAGE AND DOSAGE

Unless recommended otherwise by veterinary surgeon,

Fungusole 10% EC concentrate for emulsion is used after being diluted in a ratio of 1:50 and emulsified in a concentration of 0.2% w/v.

As dermatophytes can reach up to hair follicles, hard crusty regions should be removed first using a brush. It is recommended to administer the product on the whole body of the animal by spraying in the first administration; this would also facilitate reaching to subclinical lesions.

Cattle: 3-4 administrations can be made according to lesion structure with an interval of 3 days. Administration can be carried out by spraying or bathing.

Horse: Skin with lesion and its surroundings should be washed 4 times with an interval of 3 days.

Dogs: 4 administrations can be made by bathing or spraying with an interval of 3 days. Skin should be completely wetted by rubbing against the direction of hair during administration. It is recommended to shave the long-haired dogs before administration. The drug can be administered by bathing for smaller dogs.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

It is imperative to wait for a 6-month legal waiting period in case it is used in race horses.

UNDESIRED/SIDE EFFECTS

No undesired effects are reported when complied with the specified form and dose of administration.

DRUG INTERACTIONS

There is no known interaction in cutaneous administration.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

0.2% emulsion is tolerated well when administered cutaneously.

Use during pregnancy: No direct embryotoxic or fetotoxic effect of enilconazole was found in toxicology studies.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP): is zero days for meat and milk in cattle, and zero days for meat in horses.

CONTRAINDICATIONS

No contraindication was reported when administrated through skin.

GENERAL WARNINGS

Consult your Veterinary Surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Do not purchase the products with damaged packages.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

Appliers should wear protective overalls and rubber gloves. No food or drink should be consumed during administration. Rinse with water in case of contact with eyes and skin. Contaminated clothes should be taken off and contacted parts on hands and skin should be rinsed off before eating or drinking after administration. Administration should be carried out in a well-ventilated area. In case of accidental oral intake, immediately consult your doctor with the package insert.

STORAGE CONDITIONS AND SHELF LIFE

Store at room temperature (15 – 25 ^{o}C). Shelf life is 2 years as of the production date.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE

100 and 250 ml are offered for market in cardboard boxes and 500 and 1000 ml packages are presented in white HDPE and coex plastic containers without boxes.

PLACE AND CONDITIONS OF SALE

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 05.03.2008

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO : 05.03.2008–19/079

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk.

No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat