Flubendazol 5% Powder

50 mg/g, powder for oral administration with the feed

Target species: Pigs

Active ingredient: Flubendazole

Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co. KG, Lohner Str. 19, 49377 Vechta - Germany

Statement of the active substance(s) and other ingredient(s):
1.0 g powder contains:
Pharmacological active substance:
Flubendazole 50 mg
White to cream-coloured powder.

Indications:
For *pigs*: Infections with adult stages of *Hyostrongylus rubidus, Oesophagostomum dentatum, Ascaris suum, Trichuris suis,* as well as with larval stages of *Trichuris suis*.
Against *Strongyloides ransomi* there exists a partial effect.

Contraindications:
Do not use in animals with known hypersensitivity to the active ingredient, other benzimidazoles or excipients used.

Adverse reactions: Not known.

Target species: *Pigs*

Dosage for each species, route(s) and method of administration:
For administration with the feed.

For single use (*sows*):
5 mg flubenzole/kg body weight (b.w.)
equivalent to 1 g Flubendazol 5% Powder per 10 kg body weight

Administration for 5 to 10 days (*piglets*, *weaner* and *breeding* and *fattening pigs*):
1.2 mg flubendazole / kg body weight daily,
equivalent to 1 g Flubendazol 5% Powder per 42 kg body weight daily.

To ensure a successful treatment in case of infestation with *Hyostrongylus rubidus* and *Trichuris suis,* the treatment should be continued for 10 consecutive days.
Prior to the application, the powder is to be mixed freshly in a part of the feed in a way that a complete mixture is obtained. The mixture is to be given prior to the actual feeding.
It has to be ensured that the designated dose is taken up completely.
In animals with clearly disturbed general state of health and in animals showing inappetence, the administration of a pharmaceutical to be administered parenteral shall be preferred.
The body weight should be determined as accurately as possible to avoid underdosing.
For accurate dosage, use a suitable, calibrated measuring instrument.

Advice on correct administration:

Special warnings for each target species:

Frequent repeated use of active ingredients of one substance class of anthelmintics may favour resistance development against the entire substance class.

The following situations shall be avoided as these may lead to an increase of resistant parasites and finally to an inefficacy of treatment:

- frequent and repeated administration of an anthelmintic of the same drug class for a longer period of time;
- underdose, caused by an underestimation of the body weight, wrong administration of the veterinary pharmaceutical or inadequate adjustment of the dosage device (if applicable).

In the suspect of a resistance against anthelmintics, investigations on anthelmintic efficacy by suitable tests (e.g. egg index reduction test) shall be executed. If the test results clearly demonstrate a resistance to a certain anthelmintic, an anthelmintic of another drug class and a different mode of action shall be used.

Special precautions for use:

Special precautions for use in animals:

Not indicated.

Special safety precautions to be taken by the person administering the medicinal product to animals:

The veterinary medicinal product may cause eye irritation and skin sensibilization.

Avoid contact with the skin and/or the eyes.

When handling or during mixing, care should be taken to avoid direct contact with the skin and eyes, as well as the inhalation of dust by wearing protective goggles, impermeable gloves and a disposable half mask respirator in accordance with the European Standard EN 149 or a reusable half mask respirator according to the European Standard EN 140 with a filter according to EN 143.

Wash your hands following use.

If contact with skin and/or the eyes occurs, rinse with plenty of water.

Use during pregnancy, lactation or lay:

Teratogen effects are unlikely to occur when flubendazole is used in therapeutic doses.

Interaction with other medicinal products and other forms of interaction:

Not known.

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

Following overdosage, therapy can only be symptomatic and supportive.

There is no specific antidote against flubendazole known.

Incompatibilities:

Due to possible incompatibilities, mixing with other medicinal products should be avoided.

Withdrawal period(s):

Pigs: edible tissues: 14 days

Special storage precautions:
No special storage precautions necessary.
Keep out of reach and sight of children.
Shelf life after first opening of the container: 7 days.
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.

Special warnings:
None.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Package size: 600 g, 3 kg

Date on which the package leaflet was last approved: 09.08.2021

Marketing authorisation number: 6500555.00.00 (Germany)

For Veterinary use only.

Available on prescription only!