**FENBIVET® 4%**
Premix for medicated feed (fenbendazole)

**COMPOSITION**

<table>
<thead>
<tr>
<th>Content</th>
<th>Fenbivet® Premix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenbendazole</td>
<td>40 mg</td>
</tr>
<tr>
<td>Excipients</td>
<td>Up to 1 g</td>
</tr>
</tbody>
</table>

The product contains: Carmellose sodium, macrogoglycerol ricinoleate, corn cobs, tartrazine, ethanol*, water, purified*.

**PHARMACOLOGICAL ACTION**

Fenbendazole belongs to the group of the benzimidazole antihelmintic drugs. It has a wide spectrum of antiparasitic activity with high efficacy against gastrointestinal and lung nematodes as well as against cestodes. It is effective against both sexually mature and preimaginal forms as well as against the migrating larvae of helminthes. The mode of action of fenbendazole is based primarily on binding to nematode tubulin.

Fenbendazole has a wide safety margin and when applied at the recommended therapeutic doses it is practically non-toxic.

Absorption of fenbendazole is slow but more rapid in monogastrics, the Cmax in blood after oral treatment is around 8 hours in rats and rabbits, 24 hours in dogs and 2 to 3 days in sheep. The half-life for plasma elimination for fenbendazole in rats is 6 hours, rabbits 13 hours, dogs 15 hours and sheep 2 to 3 days.

After oral administration of fenbendazole to pigs in the dose of 5 mg/kg b.w., fenbendazole is rapidly absorbed from the alimentary tract and metabolized to its sulfoxide and sulfone. The parent compound is detected only in the samples of plasma collected 2 h after drug administration.

Fenbendazole is metabolized by oxidation of the sulfur molecule, hydroxylation of the phenyl ring and degradation of the carbamate to the armine.

Elimination of fenbendazole is predominantly by the faecal route. The liver appears to be the main target tissue in all species tested.

**INDICATIONS**

Nematodosis in all categories of pigs (growing pigs, fattening pigs and sows) caused by the parasitism of *Hyostrongylus rubidus, Ascaris suum, Oesophagostomum spp., Trichuris suis, Strongyloides ransomi, Metastrongylus spp., Stephanurus dentatus*.

**CONTRAINDICATIONS**

None established.

**MODE OF ADMINISTRATION**

Orally, incorporated into feed.

In order to reach uniform homogenization with feed it is recommended to mix the calculated amount of product (considering the prescribed dose) on stages in the following order: up to 10 kg feed; up to 100 kg feed; and up to 1000 kg feed.

*Not found in the finished product
**TARGET SPECIES**
All categories of pigs – growing pigs, fattening pigs and sows.

**DOSAGE**
The optimal dose is 5 mg/kg b.w. fenbendazole. In invasion of *Metastrongylus spp.* and *Stephanurus dentatus* the dose to be administered is 10 mg/kg b.w.

Single individual dose:
0.125 g Fenbivet® 4% premix /1 kg b.w. (= 5 mg fenbendazole)
0.250 g Fenbivet® 4% premix /1 kg b.w. (= 10 mg fenbendazole) in cases of *Metastrongylus spp.* and *Stephanurus dentatus* infestation.

**Single herd treatment:**

<table>
<thead>
<tr>
<th>Pig category</th>
<th>Fenbendazole [ppm]</th>
<th>Fenbivet® 4% premix [kg/t feed]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growing/fattening pigs (with body weight of about 20 kg and daily feed consumption of 1 kg)</td>
<td>100</td>
<td>2.5</td>
</tr>
<tr>
<td>Sows (with body weight of about 200 kg and daily feed consumption of 2 kg)</td>
<td>500</td>
<td>12.5</td>
</tr>
</tbody>
</table>

In cases of *Trichuris suis* or *Metastrongylus spp.* invasion the recommended duration of treatment is from 5 to 15 days according to the following schedule:

**Continuous treatment:**

<table>
<thead>
<tr>
<th>Pig category</th>
<th>Treatment periods [days]</th>
<th>Fenbendazole [ppm]</th>
<th>Fenbivet® 4% premix [kg/t feed]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growing/fattening pigs (with body weight of about 20 kg and daily feed consumption of 1 kg)</td>
<td>5</td>
<td>20</td>
<td>0.500</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>10</td>
<td>0.250</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>7</td>
<td>0.170</td>
</tr>
<tr>
<td>Sows (with body weight of about 200 kg and daily feed consumption of 2 kg)</td>
<td>5</td>
<td>100</td>
<td>2.500</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>50</td>
<td>1.250</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>33</td>
<td>0.830</td>
</tr>
</tbody>
</table>

If the duration of the treatment period differs from the periods given in the above table, calculate the dose as per the following formulae:

**Pigs for fattening with body weight up to 50 kg**

\[
\frac{2.5 \text{ kg}}{\text{Number of days}} = \text{kg FENBIVET® 4% premix /t feed}
\]

**Sows with body weight up to 200 kg**

\[
\frac{12.5 \text{ kg}}{\text{Number of days}} = \text{kg FENBIVET® 4% premix /t feed}
\]
SIDE EFFECTS
Not established.

WITHDRAWAL PERIOD
Meat: 3 days before slaughter of pigs.

STORAGE
In the original container in dry and well-ventilated facilities protected from direct sunlight.

PACKING
Multilayer aluminum sachet (PP/Al/PE) of 12.5 g, 125 g, 500 g or 1000 g.
Double polyethylene bag in outer 3-ply paper bag of 25 kg.

WARNING
Keep out of the reach and sight of children.
Do not eat, drink or smoke while handling the product. After use, wash hands with water and soap.