PANDEX® 1% Solution for injection (ivermectin)

**COMPOSITION**

<table>
<thead>
<tr>
<th>Content</th>
<th>PANDEX® 1% Solution for injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>0.01 g</td>
</tr>
<tr>
<td>Excipients: Benzyl alcohol, Ethyl alcohol, Propylene glycol, Water for injections</td>
<td>up to 1 ml</td>
</tr>
</tbody>
</table>

**PHARMACOLOGICAL ACTION**

Ivermectin is a strong endo- and ectoparasitic agent, which spectrum of activity covers gastrointestinal nematodes, lung worms, insects, ticks, lice, mites. It paralyses nematodes and arthropods by stimulating GABA – mediated chloride ion conductance; the result is the blocking of postsynaptic transmission of the nerve impulses. Ivermectin has no effect on trematodes and cestodes because GABA is not involved in the neurotransmission of these parasites. In general, ivermectin is active against both immature and mature stages of the susceptible species. The effect of ivermectin is irreversible and prolonged, and this may be related to sustained stimulation of GABA release. While paralysis of the parasites is the most important effect of ivermectin, the suppression of reproductive processes also may be of significance. Ivermectin is distributed well in all tissues and body fluids of the target animals. The tissue residue distribution pattern is essentially the same for all species with the highest levels in the liver, bile, fat, and the lowest - in the brain and muscle. Most of the ivermectin (at least 50%), found in the edible tissues of cattle, sheep and swine, is in unaltered form. The greater portion of ivermectin ([H]B,1a and [H]B,1b) and its metabolites is eliminated in feces in all target animals. Only 0.5% to 0.2% is excreted in urine, except that up to 5% of the dose may be excreted in the milk of the lactating animals.

**INDICATIONS**

**Cattle:** gastrointestinal and pulmonary nematodiasis (ostertagiasis, hemonchosis, trichostrongylosis, cooperiasis, parafilariasis, oesophagostomosis, bunostomiasis, nematodiriasis, dictyocaulosis); eye nematodiasis (thelaziasis); invasion with insects and acars (lice, pasture ticks), psoroptic and sarcoptic mange; hypodermiasis.

**Sheep, goats:** gastrointestinal and pulmonary nematodiasis (ostertagiasis, hemonchosis, trichostrongylosis, cooperiasis, oesophagostomosis, nematodiriasis, strongyloidiasis, chabertiosis, trichuriasis, gaigeriasis, dictyocaulosis); invasions with insects and acars (lice, *Melophagus* sp., pasture ticks, mange mites, psoroptic and chorioptic mites); oestrosis.

**Pigs:** nematodiasis (ascariasis, strongyloidiasis, hyostrongylosis, metastrongyloidosis, oesophagostomosis); invasions with lice; sarcoptic mange.

**CONTRAINDICATIONS**

This product is not for intravenous or intramuscular use. Pandex® has been developed specifically for use in cattle, pigs, sheep, and goats only. The product must not be applied to dogs of breeds Collie, Shelti and Bobtail as well as to tortoise. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs may result. Accidental injection is dangerous. Since no milk withholding period has been established, do not use in lactating cows and ewes the milk of which is intended for human consumption.
MODE OF ADMINISTRATION

*Subcutaneously.* Do not apply intramuscularly or intravenously! Inject under the loose skin in front of or behind the shoulder for cattle and in the neck for pigs, sheep, and goats. Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections.

TARGET SPECIES

Cattle, pigs, sheep, goats.

DOSAGE

For subcutaneous use. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

For cattle – 200 μg ivermectin per kg b.w.

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>50</th>
<th>100</th>
<th>150</th>
<th>200</th>
<th>250</th>
<th>300</th>
<th>350</th>
<th>400</th>
<th>450</th>
<th>500</th>
<th>550</th>
<th>600</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose volume of the preparation (ml)</td>
<td>1.0</td>
<td>2.0</td>
<td>3.0</td>
<td>4.0</td>
<td>5.0</td>
<td>6.0</td>
<td>7.0</td>
<td>8.0</td>
<td>9.0</td>
<td>10.0</td>
<td>11.0</td>
<td>12.0</td>
</tr>
</tbody>
</table>

For cattle, divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction.

For sheep and goats – 200 μg ivermectin per kg b.w.

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>25</th>
<th>50</th>
<th>75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose volume of the preparation (ml)</td>
<td>0.5</td>
<td>1.0</td>
<td>1.5</td>
</tr>
</tbody>
</table>

(in case of scab – 2 injections with a 7 day interval).

For young lambs weighing less than 12 kg administer 0.1 ml of Pandex per 5 kg. Use a syringe which can deliver as little as 0.1 ml.

For pigs – 300 μg ivermectin per kg b.w.

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>16</th>
<th>33</th>
<th>66</th>
<th>100</th>
<th>133</th>
<th>166</th>
<th>200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose volume of the preparation (ml)</td>
<td>0.5</td>
<td>1.0</td>
<td>2.0</td>
<td>3.0</td>
<td>4.0</td>
<td>5.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

The recommended dosage of Pandex® for piglets weighing less than 16 kg is 0.1 ml per 3 kg.

SIDE EFFECTS

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared without treatment.

When used to treat *Hypoderma bovis larva* (cattle grubs) in cattle, ivermectin can induce serious adverse effects by killing the larva when they are in vital areas. Larva killed in the vertebral canal can cause paralysis and staggering. Larva killed around the gullet can induce salivation and bloat. These effects can be avoided by treating for grubs immediately after the heal fly (warble fly) season or after stages of grub development where these areas would be affected.
In cattle toxic effects generally do not occur when Pandex® is injected at dosages 30 times exceeding the recommended doses. Levels of 8 mg/kg cause symptoms of ataxia, listlessness and, occasionally, death in cattle. Doses of 4 mg/kg cause symptoms of ataxia and depression in sheep. Doses of 30 mg/kg induce symptoms of toxicosis (lethargy, ataxia, tremors, lateral recumbency and mydriasis) in pigs. Neonatal pigs may be more susceptible to ivermectin overdosages, presumably due to permeability of the blood-brain barrier.

**WITHDRAWAL PERIOD**

**Meat:**
- **Cattle** – 49 days.
- **Small ruminants and pigs** – 14 days.

**Milk:** Not to be administered to lactating animals the milk of which is intended for human consumption.

**STORAGE**

Store below 25°C. Store in the original container in order to protect from light.

**PACKING**

The product is presented in 25 ml, 50 or 100 ml Type II amber glass vial, sealed with a nitrile rubber stopper supplied in a carton. One vial per carton.

**WARNING**

For cattle, divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction.

For the treatment and control of *Psoroptes ovis* (sheep scab), two injections with a seven day interval are required to treat clinical signs of scab and to eliminate living mites. Treatment of sheep scab with one injection is not recommended because although a clinical improvement may be seen, elimination of all mites may not occur.

Soft tissue swelling may occur at the injection site. For this reason, it is recommended that the product should be administered into the loose skin in front of or behind the shoulder for cattle and in the neck for pigs, sheep, and goats.

People with known hypersensitivity to ivermectin should handle the product carefully.

Take care to avoid self-injection: the product may cause local irritation and/or pain at the site of injection.

Avoid contact with eyes. Do not smoke, drink or eat while handling the product. Wash hands after use.

**FURTHER INFORMATION**

This product can be used during pregnancy and lactation. When administered to lactating females residues of ivermectin are present in the maternal milk.

In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.