SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levamisole 30% Chemifarma, 300 mg/g , powder for use in drinking water for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of product contains:

Active substance:

Levamisole mg 300

Excipients:

Qualitative composition of excipients and other constituents	
Colloidal silica	
Glucose	

White smooth-flowing powder.

3. CLINICAL INFORMATION

3.1. Target species

Pigs.

3.2. Instructions for use for each target species

Infestations sustained by adult and larval forms of *Oesophagostomum* spp., *Hystrongylus* spp., *Metastrongylus* spp. and *Ascaris suum.*

3.3. Contraindications

Do not use in subjects with severe hepatic impairments.
Do not use in case of hypersensitivity to levamisole or to one of the excipients.

3.4. Special warnings

Any unnecessary use of pesticides or use deviating from the instructions provided in the SPC may increase resistance selection and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasite species and the degree or risk INFESTATION based on its epidemiological characteristics, for each group.

3.5. Special usage precautions

Special precautions for safe use in the target species:
The use of this product must take into account local information on the sensitivity of the target parasites, where available.
Care must be taken to avoid too frequent, repeated use of anthelmintics of the same class for a long lapse of time, as this increases the risk of resistance development and the therapy may turn out to be ineffective, as may any underdosage, which may be due to underestimation of body weight or incorrect administration of the product.

Special precautions to be taken by the person administering the veterinary medicine to the animals:
Avoid direct contact with the product while handling it.
People with known hypersensitivity to levamisole must avoid any contact with the veterinary medicine.

Avoid swallowing or inhaling the product during treatment. Do not contaminate with the product food, beverages and containers intended to contain them. After use, wash your hands with soap and water. In case of eye contact, immediately wash with fresh water. In case of sickness or accidental ingestion, immediately seek medical attention, possibly showing the product's label. Do not eat, drink or smoke while using the product.

This product may lead to agranulocytosis particularly in persons with immune system abnormalities. Such persons should avoid contact with the veterinary medicine.

Special precautions for environmental protection:

Not applicable.

3.6. Adverse events

Pigs:

Frequency undetermined (it cannot be defined from the available data)	Salivation, coughing, vomiting[1]

[1] Pigs with serious infestations caused by bronchopulmonary nematodes, after treatment, may exhibit coughing and vomiting caused by the removal of worms from the lungs. However, these symptoms are temporary.

The reporting of adverse events is important, as it allows continuous monitoring of the safety of a veterinary medicine. Reports should be sent, preferably by a veterinary surgeon, to the marketing authorisation holder or the national competent authority through the national reporting system. See the label for the relevant contact details.

3.7. Use during pregnancy, lactation or egg laying
The veterinary medicinal product can be administered during pregnancy or lactation.

3.8. Interaction with other veterinary medicinal products and further forms of interaction

Avoid the simultaneous administration of anthelmintics with nicotine-similar action (e.g. pyrantel tartrate).

3.9. Routes of administration and dosage

Thoroughly dissolve the therapeutic dose in the appropriate amount of drinking water and administer it in the drink consumed in half a day or in the liquid feed of one single meal.

Pigs under 20 kg b.w.:	2.5 - 2.6 g of medicinal product/100 kg b.w. (equal to 7.5 – 8.0 mg of levamisole/kg b.w.);
pigs between 20 and 40 kg b.w.:	1.67 g of medicinal product/100 kg b.w. (equal to 5.0 mg of levamisole/kg b.w.);
pigs over 40 kg b.w.:	1.35 g of medicinal product/100 kg b.w. (equal to 4.0 mg of levamisole/kg b.w.).

N.B.: In subjects over 190 kg of live weight never exceed 2.5 g of medicinal product/head (equal to 750 mg levamisole/head).
In order to strike all the arising forms not being cured with the first treatment, it is recommended to repeat it at intervals of 14-21 days from the first one, because of hypobiosis.

Any underdosage may be ineffective and help the development of drug resistance.

In order to ensure a proper dosage, determine the body weight as precisely as possible.

If animals must be treated collectively, reasonably homogeneous groups must be formed and all the animals of a group must be treated with a dosage corresponding to the highest one.

The intake of water containing the medicinal product depends on the animals' clinical conditions. In order to obtain the correct dosage, the concentration of levamisole may need to be adjusted accordingly.

The use of duly calibrated measuring equipment is recommended.

According to the recommended dosage and to the number and weight of the animals to be treated, the exact daily concentration of the veterinary medicine must be calculated according to the following formula:

$$\frac{\text{mg of medicine/kg b.w.} \times \text{Average weight of animals to be treated per day (kg)} \times \text{Number of animals to be treated}}{\text{Mean water consumption (l)}} = \text{mg of medicine/litre of water}$$

Remove the non-medicated drinking water from the drinking troughs or the non-medicated liquid feed from the troughs and administer the medicated one until it is completely finished. Then restore the non-medicated drinking water or feed. It would be suitable to let the animals get thirsty or hungry for a few hours before administering the medicine.

Good environmental hygiene standards must be fully respected, as the nematodes re-infest the pig mainly through the contaminated litter.

3.10. Overdosage
Data not available. Do not exceed the recommended dosage.

3.11 Special restrictions on use and special conditions for use, including restrictions on the use of antimicrobial drugs and of veterinary pesticides to control the risk of developing resistance
Not applicable.

3.12. Withdrawal time
Meat and offal:
Pigs: 7 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code:
QP52AE01

4.2. Pharmacodynamics

The veterinary medicine is based on levamisole, biologically active levogyrous enantiomer of tetramisole. Levamisole is a wide range anthelmintic, active on the most common nematodes of the digestive and respiratory tract of different animal species. In fact it is active against the adult and larval stages of strongyli and the adult stages of ascarids.

Levamisole acts with a mechanism of action which is similar to the nicotine one. Thus it may cause blood pressure and intestinal motility to increase. It has a ganglion stimulating effect (acetylcholine-mimetic) and causes tonic muscular contractions paralysing the parasite, which is consequently ejected.

Resistance to one compound of an anthelmintic group automatically confers resistance to all anthelmintics of the same group.

Both levamisole and pyrantel/morantel act as cholinergic agonists and cause depolarisation of the nematode's muscle membrane.

Resistance to levamisole leads to resistance to morantel, while resistance to morantel automatically does not lead to resistance to levamisole.

4.3. Pharmacokinetics

After the oral administration, levamisole is rapidly absorbed and the peak plasma concentrations are reached after 1- 2 hours. It spreads through all the body tissues and in liver it is transformed into less active metabolites. In pigs, the half-life of levamisole after oral administration is 6.2 hours. After the administration, in the 12 hours thereafter, it is excreted by approximately 40% in urine and in the 8 days thereafter by approximately 40% in the faeces.

Levamisole neither causes photosensitisation, nor requires a particular diet before and/or after treatment. It can be administered to pregnant or lactating sows without interfering with the course of pregnancy and lactation. It has half the toxicity level of tetramisole.

The main pharmacokinetic parameters after oral administration in pigs are: maximum plasma concentration (Cmax): 1.3 µg/ml; time at which the maximum concentration is reached (Tmax): 1.3 hours; half-life (t1/ 2): 6.2 hours; area under the curve (AUC):: 13.8 µg/ml.

5. PHARMACEUTICAL INFORMATION

5.1. Main incompatibilities

As there are no compatibility studies available, do not mix this product with other veterinary medicinal products.

5.2. Shelf-life

Shelf-life of the veterinary medicinal product, as packaged for selling purposes: 24 months
Shelf-life after first opening of primary packaging: 3 months
Shelf-life after dissolution as per instructions: 12 hours.
After dissolution in liquid feed use it immediately and do not store.

5.3. Special storage precautions

Store it in a dry place.
Do not store above 25°C.

5.4. Nature and composition of primary packaging

- 1 kg white high-density polyethylene pots, with inviolable polyethylene cap provided with polyethylene undercap. At the first package opening, the seal which is an integral part of the cap is broken.
- 5 kg bags with three layers of paper and one – the inner one – of polyethylene. The bags are closed by sewing. The seal consists in a ribbon, with the mark of the company "Chemifarma" printed on it.
- 50 g three-layer bags: the outer layer in polyester, the intermediate one in aluminium and the inner one in low-density polyethylene. The bags are closed through heat-sealing.

5.5. Special precautions for the disposal of unused veterinary medicinal products or wastes resulting from their use

Medicinal products must not be disposed of in waste water or household waste.
Use collection systems for the disposal of unused veterinary medicinal products or wastes resulting from the use of such medicinal products in accordance with local regulations and any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chemifarma S.p.A.

7. MARKETING AUTHORISATION NUMBER(S)

50 g bag: AIC No.: 102887015
1 kg pot: AIC No.: 102887027
5 kg bag: AIC No.: 102887039

8. FIRST AUTHORISATION DATE

First authorisation date: 22/05/2001.

9. DATE OF LATEST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

08/2024.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
To be sold by medical-veterinary prescription only, in three copies, not reproducible.

Detailed information on this veterinary medicinal product available in the Union Medicines Database (https://medicines.health.europa.eu/veterinary/it).