SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levaveto 750 mg/g powder for use in drinking water for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active substance:

Levamisole hydrochloride	884 mg,
equivalent to levamisole base	750 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
Fine, white, homogeneous powder.

4. CLINICAL PARTICULARS

4.1 Target species
Pigs.

4.2 Indications for use, specifying the target species
For the treatment of infections by Ascaris suum (L3, L4, L5 and adult stage).

4.3 Contraindications
Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

4.4 Special warnings for each target species
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dispensing system (if any).

Ideally any suspected clinical case of resistance to anthelmintics should be further investigated using appropriate tests. Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals
Accurate dosing is fundamental since the therapeutic index of levamisole is low.
Due to lack of data the product should not be administered in pigs aged less than 10 weeks.
Since the product is excreted via the bile and kidneys, some caution is advisable in animals with liver or kidney diseases.

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

The product may be irritating to the skin and eyes, and harmful if inhaled or swallowed. It can cause cutaneous hypersensitivity.
When handling or mixing, care should be taken to avoid direct contact with the skin and eyes, and inhalation of dust, by wearing goggles, impervious gloves and a dust mask (a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143). Wash off accidental splashes immediately with water. Do not smoke, drink or eat while handling the product. Wash hands after use.
People with known hypersensitivity to levamisole should avoid contact with the veterinary medicinal product.
In case of inhalation, breathe in fresh air. If breathing difficulty develops, consult a physician.
In case of accidental eye contact, wash the eyes with plenty of water for 15 minutes.
In case of accidental swallowing, rinse the mouth with water if the person is conscious. Seek medical advice immediately and show the leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
Transient vomiting and salivation were commonly reported in some literature studies following oral treatment with levamisole. During the product-specific studies one isolated case of vomiting was observed following treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction
Nicotinic agonists (such as tetrahydropyrimidines) and inhibitors of cholinesterases (such as organophospates) increase nicotinic effects resulting in increased toxicity of levamisole. The effect of depolarising neuromuscular blocking agents will be intensified by levamisole. Based on chemical incompatibilities, neomycin, sulphonamides, and tetracyclines should not be used concomitantly with this veterinary medicinal product.

4.9 Amounts to be administered and administration route
For oral administration, via the drinking water.

The recommended dosage is 10 mg levamisole base / kg BW, corresponding to a dosage of 13.3 mg product.
The product is intended for single administration in a limited volume of drinking water.
To ensure the consumption of the medicated drinking water, it is recommended that the animals should not be given any drinking water at night. In this way the limited volume of medicated drinking water shall be drunk in a time interval of 2 to maximum 6 hours (average time: 3 hours).
The use of calibrated scales is strongly recommended to obtain correct dosages.

The following table can be used for preparing the medicated drinking water:

Quantity of the product	***Volume of medicated drinking water***	***Total body weight of pigs to be treated***
10 g	20 L	750 kg

1 sachet of 100 g	200 L	7500 kg
1 bag of 1 kg	2000 L	75,000 kg

These solutions contain approximately 375 ppm levamisole.

When used in dispensing systems intended for further dilution of the product in drinking water, solutions up to 100 g per litre may be used. At concentrations of 10 g per litre and higher, a slight cloudy solution is formed. This is due to the presence of certain excipients and does not in any way suggest a problem with the solution. In addition, because the particles are colloidal (microscopically small dispersed, insoluble particles), there is no risk of clogging of dispensing systems and pipelines.

After administration of the medicated drinking water, the consumption of normal drinking water is resumed.

- To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dispensing system (e.g. dosing pump) should be checked.
- When the animals are to be treated collectively rather than individually, they must be grouped according to their body weight and dosed correspondingly to avoid under- or overdosing.
- The medicated water should be freshly prepared. Only sufficient medicated drinking water should be prepared to cover the daily requirements.
- During treatment all animals must have unrestricted access to adequate numbers of drinking trough with medicated water.
- The maximum solubility of the product in soft and hard water at both 4°C and 20°C is 100 g/L.

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

Levamisole overdosage can increase the probability of occurrence of the signs mentioned in 4.6 (e.g. salivation and vomiting), and can cause other nervous signs like tremor, ataxia, frequent urination/defecation, depression and collapse.
Possible signs of toxicosis relate to the action of levamisole as a nicotinic agonist, which consist in neuromuscular and parasympathetic stimulation, and in central depression. Part of those signs can be antagonized using atropine or glycopyrrolate. Oxygenotherapy might be necessary to support the respiratory function.

Levamisole has been reported to stimulate the immune system. Repeated dosing can lead to sensitisation and may result in severe adverse reactions, i.e. anaphylactic shock.

In a tolerance study performed with single administration of the product in a group of 5 pigs, during the first days after treatment with a dose of 125 mg levamisole/kg BW, slight changes in behaviour (behaviour less active and alert), a lower heart rate, a lower respiration rate and up to a 50% decrease in the normal feed intake were noted. These adverse effects are transient.

4.11 Withdrawal period(s)

Meat and offal: 21 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, imidazothiazoles
ATC vet code: QP52AE01

5.1 Pharmacodynamic properties

Levamisole is an ionotropic cholinergic agonist that selectively produces depolarization of nematode muscle cell and spastic contraction. Levamisole binds to acetylcholine receptors of the nicotinic type, which results in a great increase in the permeability of the post-synaptic membrane for small cations, such as Na^+, K^+ and to a smaller extent Ca^{2+}. The influx of sodium ions causes depolarization of the postsynaptic membrane of the muscle cells, resulting in an action potential and in rapid,

sustained contractions. This depolarization is dose-dependent. The nicotinic receptors remain activated for a long time by levamisole, since in contrast to acetylcholine, it is not inactivated by acetylcholinesterase. The prolonged depolarization results in loss of electrical excitability of the ion channels and consequently the channels are no longer opened by a depolarizing stimulus. Consequently levamisole leads to neuromuscular blockade of the depolarizing type and to the spastic paralysis of the parasite, which is then readily expelled by the normal intestinal peristalsis of the host. Levamisole acts selectively on the nicotinic receptors of nematodes, which exhibit differences in their substructure from these receptors in the host.

5.2 Pharmacokinetic particulars

Levamisole is readily absorbed by the oral route. After extensive metabolisation in the liver it is mostly eliminated within a few days. The main part of the dose is eliminated in urine, but a significant part is also eliminated via the bile.

In a pharmacokinetic study conducted with the product, after administration of the single therapeutic dose of 10 mg levamisole/kg BW via the drinking water to pigs, a plasma peak, C_{max}, of 1.32 µg/ml ± 0.38 µg/ml was reached at a T_{max} of 2.57 ± 1.87 h. The administration of levamisole should be completed within a short time frame, so that a high concentration of this cholinergic agonist is reached. The mean plasma elimination half-life $t_{1/2el}$ was 8.69 h, corresponding to an elimination constant k_{el} of 0.08 h^{-1}.
In a bioavailability study performed with the product, after bolus administration of the therapeutic dose of 10 mg levamisole/kg BW, a plasma peak C_{max}, of 3.025 ± 1.293 µg/ml was reached at a T_{max} of 0.993 ± 0.973 h. The mean plasma elimination half-life $t_{1/2el1}$ was 0.005h and $t_{1/2el2}$ was 5.29 h, corresponding to an elimination constant k_{el} of 42.111 h^{-1}. The mean values from this study resulted after oral administration in an absolute bioavailability of 85.3 +/-13.9%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Colloidal silica, anhydrous.
- Lactose monohydrate.

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.
After first opening, keep the container tightly closed.

6.5 Nature and composition of immediate packaging

100g bag: multilayer bag of polyester (outer layer) – polyethylene low density/aluminium/ polyethylene low density – polyethylene low density (inner layer).
1000g bag: multilayer bag of polyester (outer layer) – aluminium – polyethylene low density (inner layer).

Bag of 100g
Bag of 1000g
Box of 10 bags of 100g

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

V.M.D. n.v.
Hoge Mauw 900
B-2370 Arendonk

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

{DD/MM/YYYY}

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levaveto 750 mg/g powder for use in drinking water for pigs.
Levamisoli hydrochloridum.

2. STATEMENT OF ACTIVE SUBSTANCES

1 g contains: Levamisoli hydrochloridum 884 mg eq. levamisolum 750 mg

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

10 x 100 g

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The recommended dosage is 10 mg levamisole base / kg BW., which corresponds to a dose of 13.3 mg product.
The product is intended for single administration in a limited volume of drinking water.
After administration of the medicated drinking water, the consumption of normal drinking water is resumed.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once opened: use within 6 months.

Once reconstituted: 24 hours.

Only for Poland:
Termin ważności (EXP) {month/year}

11. SPECIAL STORAGE CONDITIONS

After first opening, keep the container tightly closed.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

Only for Poland:
Wyłącznie dla zwierząt
Wydawany z przepisu lekarza – Rp.
Do podawania pod nadzorem lekarza weterynarii.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.
Hoge Mauw 900
B-2370 Arendonk

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Only for Poland:
Nr serii (Lot) {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100g: multilayer bag of polyester (outer layer) – polyethylene low density/aluminium/ polyethylene low density – polyethylene low density (inner layer).
1000g: multilayer bag of polyester (outer layer) – aluminium – polyethylene low density (inner layer).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levaveto 750 mg/g powder for use in drinking water for pigs.
Levamisoli hydrochloridum.

2. STATEMENT OF ACTIVE SUBSTANCES

1 g contains: Levamisoli hydrochloridum 884 mg eq. levamisolum 750 mg

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g and 1 kg.

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The recommended quantity is 10 mg levamisole base / kg BW., which corresponds to a dose of 13.3 mg product.
The product is intended for single administration in a limited volume of drinking water.
After administration of the medicated drinking water, the consumption of normal drinking water is resumed.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened: use within 6 months.
Once reconstituted: 24 hours.

11. SPECIAL STORAGE CONDITIONS

After first opening, keep the container tightly closed.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

Only for Poland:
Wyłącznie dla zwierząt
Wydawany z przepisu lekarza – Rp.
Do podawania pod nadzorem lekarza weterynarii.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.
Hoge Mauw 900
B-2370 Arendonk

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET
Levaveto 750 mg/g powder for use in drinking water for pigs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk.
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levaveto 750 mg/g powder for use in drinking water for pigs.
Levamisole hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each g contains:
Active substance:

Levamisole hydrochloride	884 mg,
equivalent to levamisole base	750 mg

Excipients:
- Colloidal silica, anhydrous.
- Lactose monohydrate.

Fine, white, homogeneous powder.

4. INDICATION(S)

For the treatment of infections by Ascaris suum (L3, L4, L5 and adult stage).

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

6. ADVERSE REACTIONS

Transient vomiting and salivation were commonly reported in some literature studies following oral treatment with levamisole. During the product-specific studies one isolated case of vomiting was observed following treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system which can be found on the website of
Belgium: Federal agency for medicines and health products - www.fagg-afmps.be/en/
Estonia: State Agency of Medicines - www.ravimiamet.ee
Germany: Federal Office of Consumer Protection and Food Safety - www.bvl.bund.de
France: ANMV – Agence Nationale du Médicament Vétérinaire, Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail - www.anses.fr
Hungary: National Food Chain Safety Office, Directorate of Veterinary Medicinal Products - http://www.nebih.gov.hu/en/specialities/veterinary
Latvia: Food and Veterinary Service - www.pvd.gov.lv
Lithuania: National Food and Veterinary Risk Assessment Institute - www.nmvrvi.lt
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products - www.urpl.gov.pl
Romania: Institute for Control of biological products and veterinary medicines - www.icbmv.ro/
The Netherlands: Medicines Evaluation Board - www.cbg-meb.nl

7. TARGET SPECIES

Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration, via the drinking water.

The recommended dosage is 10 mg levamisole base / kg BW, corresponding to a dosage of 13.3 mg product.
The product is intended for single administration in a limited volume of drinking water.
To ensure the consumption of the medicated drinking water, it is recommended that the animals should not be given any drinking water at night. In this way the limited volume of medicated drinking water shall be drunk in a time interval of 2 to maximum 6 hours (average time: 3 hours).
The use of calibrated scales is strongly recommended to obtain correct dosages.

The following table can be used for preparing the medicated drinking water:

Quantity of the product	***Volume of medicated drinking water***	***Total body weight of pigs to be treated***
10 g	20 L	750 kg
1 sachet of 100 g	200 L	7500 kg
1 bag of 1 kg	2000 L	75,000 kg

These solutions contain approximately 375 ppm levamisole.

When used in dispensing systems intended for further dilution of the product in drinking water, solutions up to 100 g per litre may be used. At concentrations of 10 g per litre and higher, a slight cloudy solution is formed. This is due to the presence of certain excipients and does not in any way suggest a problem with the solution. In addition, because the particles are colloidal (microscopically small dispersed, insoluble particles), there is no risk of clogging of dispensing systems and pipelines.

After administration of the medicated drinking water, the consumption of normal drinking water is resumed.

- To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dispensing system (e.g. dosing pump) should be checked.
- When the animals are to be treated collectively rather than individually, they must be grouped according to their body weight and dosed correspondingly to avoid under- or overdosing.
- The medicated water should be freshly prepared. Only sufficient medicated drinking water should be prepared to cover the daily requirements.
- During treatment all animals must have unrestricted access to adequate numbers of drinking trough with medicated water.
- The maximum solubility of the product in soft and hard water at both 4°C and 20°C is 100 g/L.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and offal: 21 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.
After first opening, keep the container tightly closed.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dispensing system (if any).

Ideally any suspected clinical case of resistance to anthelmintics should be further investigated using appropriate tests. Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Special precautions for use in animals
Since the product is excreted via the bile and kidneys, some caution is advisable in animals with liver or kidney diseases.
Accurate dosing is fundamental since the therapeutic index of levamisole is low.
Due to lack of data the product should not be administered in pigs aged less than 10 weeks.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product may be irritating to the skin and eyes, and harmful if inhaled or swallowed. It can cause cutaneous hypersensitivity.

When handling or mixing, care should be taken to avoid direct contact with the skin and eyes, and inhalation of dust, by wearing goggles, impervious gloves and a dust mask (a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143). Wash off accidental splashes immediately with water. Do not smoke, drink or eat while handling the product. Wash hands after use.
People with known hypersensitivity to levamisole should avoid contact with the veterinary medicinal product.
In case of inhalation, breathe in fresh air. If breathing difficulty develops, consult a physician.
In case of accidental eye contact, wash the eyes with plenty of water for 15 minutes.
In case of accidental swallowing, rinse the mouth with water if the person is conscious. Seek medical advice immediately and show the leaflet or the label to the physician.

Pregnancy:
Can be used during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Nicotinic agonists (such as tetrahydropyrimidines) and inhibitors of cholinesterases (such as organophospates) increase nicotinic effects resulting in increased toxicity of levamisole. The effect of depolarising neuromuscular blocking agents will be intensified by levamisole. Based on chemical incompatibilities neomycin, sulphonamides, and tetracyclines should not be used concomitantly with this veterinary medicinal product.

Overdose (symptoms, emergency procedures, antidotes):
Levamisole overdosage can increase the probability of occurrence of the signs mentioned in 6. (e.g. salivation and vomiting), and can cause other nervous signs like tremor, ataxia, frequent urination/defecation, depression and collapse.
Possible signs of toxicosis relate to the action of levamisole as a nicotinic agonist, which consist in neuromuscular and parasympathetic stimulation, and in central depression. Part of those signs can be antagonized using atropine or glycopyrrolate. Oxygenotherapy might be necessary to support the respiratory function.
Levamisole has been reported to stimulate the immune system. Repeated dosing can lead to sensitisation and may result in severe adverse reactions, i.e. anaphylactic shock.
In a tolerance study performed with single administration of the product in a group of 5 pigs, during the first days after treatment with a dose of 125 mg levamisole/kg BW, slight changes in behaviour (behaviour less active and alert), a lower heart rate, a lower respiration rate and up to a 50% decrease in the normal feed intake were noted. These adverse effects are transient.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

100g bag : multilayer bag of polyester (outer layer) – polyethylene low density/aluminium/ polyethylene low density – polyethylene low density (inner layer).
1000g bag: multilayer bag of polyester (outer layer) – aluminium – polyethylene low density (inner layer).

Bag of 100g
Bag of 1000g
Box of 10 bags of 100g
Not all pack sizes may be marketed.