1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECOMECTIN 18.7 mg/g Oral Paste for Horses (IE, UK)
IVERMAX 18.7 mg/g Oral Paste for Horses (BE, NL)
DOPHAMEC EQUI 18.7 mg/g Oral Paste for Horses (DE)
ANIMEC 18.7 mg/g Oral Paste for Horses (ES)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Ivermectin 18.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product>**
Titanium dioxide (E171)	20 mg
Hydrogenated Castor Oil	
Hydroxypropylcellulose GF	
Propylene Glycol	

White homogeneous paste

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Treatment of nematode or arthropod infection due to:

Large strongyles:
Strongylus vulgaris (adults and L_4 stage larvae [arterial])
Strongylus edentatus (adults and L_4 stage larvae [tissue])
Strongylus equinus (adults)

Small strongyles (including benzimidazole resistant strains):
Cyathostomum spp. (adults and luminal L_4 stage larvae)
Cylicocyclus spp. (adults and luminal L_4 stage larvae)
Cylicodontophorus spp. (adults and luminal L_4 stage larvae)
Cylicostephanus spp. (adults and luminal L_4 stage larvae)
Gyalocephalus spp. (adults and luminal L_4 stage larvae)

Ascarids:
Parascaris equorum (luminal L_5 larvae and adults)

Pinworms:
Oxyuris equi (L_4 stage larvae and adults)

Neck threadworms:

Onchocerca spp. (microfilariae)

Stomach bots:
Gasterophilus spp. (oral and gastric stages)

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs or cats as severe adverse reactions may occur.

3.4 Special warnings

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema and pruritus following treatment, such reactions are assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days, but symptomatic treatment may be advisable.

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 body weight or misadministration of the veterinary medicinal product.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). 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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a veterinary medicinal product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

Resistance to ivermectin has been reported in *Parascaris equorum*. Therefore, the use of this veterinary medicinal product should be based on local farm epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

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

Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.
This veterinary medicinal product may cause skin and eye irritation. Therefore, the user should avoid contact of the veterinary medicinal product with the skin and the eyes. In case of contact, rinse immediately with plenty of water.
In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Dogs and cats should not be allowed to ingest spilled paste or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity.
The veterinary medicinal product has been formulated for use in horses only. Cats, dogs (especially Collies, Old English Sheepdogs and related breeds or crosses) and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this veterinary medicinal product if they are allowed to ingest spilled paste or have access to used syringes.

3.6 Adverse events

Horses:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

3.9 Administration routes and dosage

Oral use.
Dosage:
One syringe division of paste/100 kg body weight (based on a recommended dosage of 0.2 mg ivermectin per kg body weight).
The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.
The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Administration:
The paste is given by oral route.

To ensure a correct dosage, body weight should be determined as accurately as possible. The animal's mouth should be free from food to ensure swallowing. Turn the screw gauge on the syringe plunger to the body weight of the horse. The tip of the syringe barrel should be inserted at the interdental space (the gap between the front and back teeth) and the paste deposited on the base of the tongue. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.
Immediately elevate the horse's head for a few seconds to ensure swallowing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. Although no antidote has been identified, symptomatic therapy may be beneficial.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 34 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, which results in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels, and macrocyclic lactones do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

Following oral administration of the recommended dose to horses, a mean peak plasma concentration (C_{max}) of 33 ng/ml was achieved within 24 hours.

Ivermectin is well absorbed into the systemic circulation following administration. Only about 2% of the drug is excreted in urine, faecal excretion being the major route of elimination.

Ivermectin passes readily into milk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Do not store above 25ºC

5.4 Nature and composition of immediate packaging

Polyethylene dose graduated syringes in an outer carton box.

Pack size:
Box containing 1 syringe of 6.42 g
Box containing 1 syringe of 7.49 g
Box containing 50 syringes of 7.49 g

Not all pack sizes may be marketed.

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

The veterinary medicinal product should not enter water courses as ivermectin is EXTREMELY DANGEROUS TO FISH AND OTHER AQUATIC ORGANISMS.
Medicines should not be disposed of via wastewater or household waste. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

ACME DRUGS s.r.l.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

05/01/2007

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

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECOMECTIN 18.7 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Ivermectin 18.7 mg

3. PACKAGE SIZE

6.42 g
7.49 g
50 x 7.49 g

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 34 days.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

ACME DRUGS s.r.l.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECOMECTIN

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each g of paste contains 18.7 mg of ivermectin

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ECOMECTIN 18.7 mg/g Oral Paste for Horses

2. Composition

Each g contains:

Active substance:
Ivermectin 18.7 mg

Excipients:
Titanium dioxide (E171) 20 mg

White homogeneous paste

3. Target species

Horses.

4. Indications for use

Treatment of nematode or arthropod infection due to:

Large strongyles:
Strongylus vulgaris (adults and L_4 stage larvae [arterial])
Strongylus edentatus (adults and L_4 stage larvae [tissue])
Strongylus equinus (adults)

Small strongyles (including benzimidazole resistant strains):
Cyathostomum spp. (adults and luminal L_4 stage larvae)
Cylicocyclus spp. (adults and luminal L_4 stage larvae)
Cylicodontophorus spp. (adults and luminal L_4 stage larvae)
Cylicostephanus spp. (adults and luminal L_4 stage larvae)
Gyalocephalus spp. (adults and luminal L_4 stage larvae)

Ascarids:
Parascaris equorum (luminal L_5 larvae and adults)

Pinworms:
Oxyuris equi (L_4 stage larvae and adults)

Neck threadworms:
Onchocerca spp. (microfilariae)

Stomach bots:
Gasterophilus spp. (oral and gastric stages)

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs or cats as severe adverse reactions may occur.

6. Special warnings

Special warnings:
Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema (swelling) and pruritus (itching) following treatment. Such reactions are assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable
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 body weight or misadministration of the veterinary medicinal product.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). 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.
Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a veterinary medicinal product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.
Resistance to ivermectin has been reported in *Parascaris equorum.* Therefore, the use of this veterinary medicinal product should be based on local farm epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

Special precautions for safe use in the target species:
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.
This veterinary medicinal product may cause skin and eye irritation. Therefore, the user should avoid contact of the veterinary medicinal product with the skin and the eyes. In case of contact, rinse immediately with plenty of water.
In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:
Dogs and cats should not be allowed to ingest spilled paste or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity
The veterinary medicinal product has been formulated for use in horses only. Cats, dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this veterinary medicinal product if they are allowed to ingest spilled paste or have access to used syringes.

Pregnancy and lactation:
Can be used during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

The effects of GABA agonists are increased by ivermectin.

Overdose:
Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis (dilation of the pupil), ataxia (incoordination), tremors (shaking), stupor (dull), coma and death. The less severe signs have been transitory.
Although no antidote has been identified, symptomatic therapy may be beneficial.

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

7. Adverse events

Horses

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Dosage:
One syringe division of paste/100 kg body weight (based on a recommended dosage of 0.2 mg ivermectin per kg body weight). The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.
The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Administration:
The paste is given by oral route.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible. The animal's mouth should be free from food to ensure swallowing. Turn the screw gauge on the syringe plunger to the body weight of the horse. The tip of the syringe barrel should be inserted at the interdental space (the gap between the front and back teeth) and the paste deposited on the base of the tongue. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.
Immediately elevate the horse's head for a few seconds to ensure swallowing.

10. Withdrawal periods

Meat and offal: 34 days.
Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C

Shelf life after first opening the immediate packaging: use immediately.

Do not use this veterinary medicinal product after expiry date which is stated on the label/carton after EXP. The expiry date refers to the last day of that month.

12. Special precautions for disposal

The veterinary medicinal product should not enter water courses as ivermectin is EXTREMELY DANGEROUS TO FISH AND OTHER AQUATIC ORGANISMS.
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack size:
Carton box with 1 syringe of 6.42 g
Carton box with 1 syringe of 7.49 g
Carton box with 50 syringes of 7.49 g

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:

ACME DRUGS s.r.l.
Via Portella della Ginestra 9,
42025 Cavriago,
Italy
Tel: +39 0522 942780
info@acmedrugs.eu

Pharmacovigilance@acmedrugs.eu

<Local representatives and contact details to report suspected adverse events:>