ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQVALAN DUO, oral paste (AT, BE, CY, CZ, DE, EE, EL, ES, FR, HU, IS, IE, IT, LV, LT, LU, NL, PT, SI, SK XI)
IVOMEC COMP, oral paste (DK, FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Ivermectin.....15.5 mg
Praziquantel.....77.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ttitanium dioxide (E171)	*20 mg*
Sunset Yellow (E110)	*0.40 mg*
Buthylhydroxyanisole (E320)	*0.20 mg*
Hydroxypropylcellulose	
Hydrogenated castor oil	
Glycerol formal	

Smooth, homogeneous orange paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment of mixed cestode and nematode or arthropod infestations in horses. The following parasites of horses are sensitive to the antiparasitic effects of the veterinary medicinal product:

Adult Tapeworms:
Anoplocephala perfoliata
Anoplocephala magna

Large strongyles:
Strongylus vulgaris (adults and arterial larval stages)
Strongylus edentatus (adults and tissue larval stages)
Strongylus equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus
Craterostomum acuticaudatum (adults)

Adult and immature (intraluminal fourth-stage larvae) of small strongyles or cyathostomes, including benzimidazole-resistant strains:

Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus
Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum
Cylicocyclus spp.
Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
Cylicostephanus spp.
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Parapoteriostomum spp.
Parapoteriostomum mettami
Petrovinema spp.
Petrovinema poculatum
Poteriostomum spp.

Adult hairworms: *Trichostrongylus axei*
Adult and immature (fourth stage Larvae) pinworms: *Oxyuris equi*
Adult, third- and fourth-stage larvae of roundworms (ascarids): *Parascaris equorum*
Microfilariae of neck threadworms: *Onchocerca* spp.
Adult intestinal threadworms: *Strongyloides westeri*
Adult large-mouth stomach worms: *Habronema muscae*
Oral and, gastric stages of bots: *Gasterophilus* spp.
Adult and immature (inhibited fourth stage larvae) lungworms: *Dictyocaulus arnfieldi*

3.3 Contraindications

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.

3.4 Special warnings

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, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device (if any).

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.

Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of gastro-intestinal 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:
Safety studies were not conducted in foals younger than 2 months of age, or in stallions, the use of the veterinary medicinal product, is not recommended in these categories of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Do not smoke, drink or eat while handling the veterinary medicinal product.
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 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.

3.6 Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Oedema[1] Pruritus[1] Inflammation of the mouth, lip and tongue (e.g.,lip erythema, lip oedema, tongue oedema, tongue inflammation, tongue disorders, stomatitis, hypersalivation)[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Abdominal discomfort (colic, loose stool)

[1]Can occur for some horses with heavy infestation of *Onchocerca* spp. microfilariae following the treatment; such reactions were assumed to be the result of the death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.
[2]These reactions have been transitory in nature, appearing within 1 hour and abating within 24 to 48 hours following administration. In case of severe oral reactions symptomatic treatment is recommended.

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

Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of either ivermectin or praziquantel at the recommended doses during therapy.

Ivermectin-Praziquantel combination can be used after the first three months of gestation and during lactation. In the absence of clinical data in early pregnancy the veterinary medicinal product can only be used in the first three months of gestation according to a risk benefit analysis by the veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration route and dosage

Oral use.

Dosage:
The recommended dosage is 200 mcg/kg bw of ivermectin and 1 mg/kg bw of praziquantel corresponding to 1.29 g of paste per 100 kg bodyweight in a single administration.
Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg, calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger.

Method of administration:
To ensure a correct dosage, body weight should be determined as accurately as possible.

While holding the plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the stop ring is at the prescribed weight marking. Lock the ring in place by turning it ¼ turn to the right in order to bring the two arrows, the one visible on the ring and the one on the plunger rod, into alignment.
Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing and ensure that the paste is consumed.

Parasite control Program:
Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

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

No undesirable effects related to treatment were observed in 2 months old horses treated with the veterinary medicinal product at up to three times the recommended dose and in adult horses treated at ten times the recommended dose.

Transient decreased food consumption, increased body temperature, salivation and impairment of vision were noticed in horses treated twice with an ivermectin oral paste or once with the veterinary medicinal product at ten times the recommended dose (i.e., 2 mg/kg b.w.). All changes disappeared within five days.

No antidote has been identified; however, 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: 30 days.
Not authorised for use in animal producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA51

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.

Praziquantel is a synthetic isoquinoline-pyrazine derivative with activity against several trematode and cestode parasites. *In vitro* and *in vivo* studies have found that trematodes and cestodes rapidly take up praziquantel within minutes; praziquantel causes tetanic contraction of the parasites' musculature and a rapid vacuolisation of their tegument. The net effect is that the parasite detaches from the host. Praziquantel affects membrane permeability in trematodes and cestodes, and influences divalent cation fluxes, particularly calcium ion homeostasis, which is thought to contribute to the rapid muscle contraction and vacuolisation. The margin of safety for the praziquantel is due to its rapid metabolism and excretion as well as its selective effect on susceptible parasites.

4.3 Pharmacokinetics

After oral administration to horses of the recommended dose of the veterinary medicinal product, praziquantel is rapidly absorbed and excreted, whereas ivermectin is more slowly absorbed and persists during a longer period in the body. Praziquantel maximum plasma concentrations (of the order of 1 µg/ml) are reached rapidly (approximately in the hour following treatment). The praziquantel plasma residue depletes rapidly to non-quantifiable levels by 7.5 hours post dose. Praziquantel is excreted as metabolites in the urine and faeces and the total amount excreted accounts for 31% and 24%, respectively of the administered dose within 24 hours.

Ivermectin maximum plasma concentrations (C_{max}: 37.9 ng/ml) are reached in a longer period (t_{max}: approximately 9 hours after treatment) and levels fell to non-detectable / no quantifiable values on or before 28 days after administration.
Faecal excretion is the major pathway of ivermectin elimination in all species studied.
No pharmacological interference between ivermectin and praziquantel was noted.

Environmental properties

EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE (see also section 5.5)

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

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: 2 years

5.3 Special precautions for storage

Store in the original container.
Replace the cap after use.

5.4 Nature and composition of immediate packaging

Immediate package:
The veterinary medicinal product is available in syringes containing 7.74 g, 9.68 g or 14.19 g of paste:

For syringe intended for the treatment of horses up to 600 kg, containing 7.74 g of paste: White polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a white polypropylene plunger rod, with dose divisions calibrated by body weight with an orange polypropylene stop ring.

For syringes intended for the treatment of horses up to 750 kg and 1100 kg, containing 9.68 g or 14.19 g of paste respectively: White polypropylene syringes barrel with an orange rubber cap, a rubber rod tip and a white polypropylene plunger rod, with dose divisions calibrated by body weight with an orange polypropylene stop ring.

Outer package and sales presentations:
Each syringe is sealed in a transparent polypropylene bag.

Carton box of 1 syringe for oral administration of 7.74g
Carton box of 1 syringe for oral administration of 9.68g
Carton box of 1 syringe for oral administration of 14.19g
Carton box of 50 syringes for oral administration of 7.74g
Carton box of 50 syringes for oral administration of 9.68g
Carton box of 50 syringes for oral administration of 14.19g

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water course as ivermectin and praziquantel may be dangerous for fish and other aquatic organisms.

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

To be completed nationally

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

To be completed nationally

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

To be completed nationally

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 (of 1 or 50 Syringes)

CASE N°1: *The text below corresponds to the cases where all the information of the package leaflet can not be conveyed on the outer packaging and the container* ***(for example for multilingual packaging)****. Consequently a package leaflet is added (see the corresponding template).*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQVALAN DUO, oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Ivermectin: 15.5 mg
Praziquantel: 77.5 mg

3. PACKAGE SIZE

1 syringe of 7.74 g
1 syringe of 9.68 g
1 syringe of 14.19 g

50 syringes of 7.74 g
50 syringes of 9.68 g
50 syringes of 14.19 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 30 days
Not authorised for use in animal producing milk for human consumption.

8. EXPIRY DATE

Exp.: {month/year}
Once opened, use within 2 years.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Replace the cap after use.

10. THE WORD "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

To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

Carton box (1 or 50 syringes)

CASE N°2: *The text below corresponds to the cases where all the information of the package leaflet CAN be conveyed on the outer packaging and container. Consequently, in that case, no separate leaflet is provided in compliance with the current QRD Template*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQVALAN DUO, oral paste

2. COMPOSITION

Each g contains:

Active substance:
Ivermectin: 15.5 mg
Praziquantel: 77.5 mg

Excipients:
Titanium oxide (E171): 20 mg
Sunset yellow FCF (E110): 0.40 mg
Butylhydroxyanisole (E320): 0.20 mg

Smooth, homogeneous orange paste.

3. PACKAGE SIZE

1 syringe of 7.74 g, 9.68 g or 14,19 g .
50 syringes of 7.74 g, 9.68 g or 14,19 g

4. TARGET SPECIES

Horses.

5. INDICATIONS FOR USE

Indications for use
For the treatment of mixed cestode and nematode or arthropod infestations in horses. The following parasites of horses are sensitive to the antiparasitic effects of the veterinary medicinal product:
Adult Tapeworms: *Anoplocephala perfoliata, Anoplocephala magna*
Large strongyles: *Strongylus vulgaris* (adults and arterial larval stages), *Strongylus edentatus* (adults and tissue larval stages), *Strongylus equinus* (adults), *Triodontophorus spp.* (adults), *Triodontophorus brevicauda, Triodontophorus serratus, Craterostomum acuticaudatum* (adults).
Adult and immature (intraluminal fourth-stage larvae) of small strongyles or cyathostomes, including benzimidazole-resistant strains: *Coronocyclus* spp., *Coronocyclus coronatus,Coronocyclus labiatus,Coronocyclus labratus, Cyathostomum* spp., *Cyathostomum catinatum, Cyathostomum pateratum,Cylicocyclus* spp., *Cylicocyclus ashworthi, Cylicocyclus elongates, Cylicocyclus insigne, Cylicocyclus leptostomum, Cylicocyclus nassatus, Cylicodontophorus*

spp., *Cylicodontophorus bicornatus, Cylicostephanus* spp., *Cylicostephanus calicatus, Cylicostephanus goldi, Cylicostephanus longibursatus, Cylicostephanus minutes, Parapoteriostomum* spp., *Parapoteriostomum mettami, Petrovinema* spp., *Petrovinema poculatum, Poteriostomum* spp.,
Adult hairworms: *Trichostrongylus axei*.
Adult and immature (fourth stage Larvae) pinworms: *Oxyuris equi.*
Adult, third- and fourth-stage larvae of roundworms (ascarids): *Parascaris equorum.*
Microfilariae of neck threadworms: *Onchocerca* spp. **Adult intestinal threadworms**: *Strongyloides westeri.*
Adult large-mouth stomach worms: *Habronema muscae.*
Oral and, gastric stages of bots: *Gasterophilus* spp.
Adult and immature (inihibited fourth stage larve) lungworms: *Dictyocaulus arnfieldi.*

6. CONTRAINDICATIONS

Contraindications
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.

7. SPECIAL WARNINGS

Special warnings
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, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device (if any).

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.

Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of gastro-intestinal nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
Safety studies were not conducted in foals younger than 2 months of age, or in stallions, the use of the veterinary medicinal product, is not recommended in these categories of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Do not smoke, drink or eat while handling the veterinary medicinal product.
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 case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of either ivermectin or praziquantel at the recommended doses during therapy.

Ivermectin-Praziquantel combination can be used after the first three months of gestation and during lactation. In the absence of clinical data in early pregnancy the veterinary medicinal product can only be used in the first three months of gestation according to a risk benefit analysis by the veterinarian.

Overdose:
No undesirable effects related to treatment were observed in 2 months old horses treated with the veterinary medicinal product at up to three times the recommended dose and in adult horses treated at ten times the recommended dose.

Transient decreased food consumption, increased body temperature, salivation and impairment of vision were noticed in horses treated twice with an ivermectin oral paste or once with the veterinary medicinal product at ten times the recommended dose (i.e., 2 mg/kg b.w.). All changes disappeared within five days.

No antidote has been identified; however, symptomatic therapy may be beneficial.

8. ADVERSE EVENTS

Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):
Oedema[1]
Pruritis[1]
Inflammation of the mouth, lip and tongue (e.g., lip erythema, lip oedema, tongue oedema, tongue inflammation, tongue disorders, stomatitis, hypersalivation)[2].

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Abdominal discomfort (colic, loose stool).

[1]Can occur in some horses with heavy infections of *Onchocerca* spp. microfilariae following the treatment; such reactions were assumed to be the result of the death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.
[2]These reactions have been transitory in nature, appearing within 1 hour and abating within 24 to 48 hours following administration. In case of severe oral reactions symptomatic treatment is required.

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 authorization holder or its local representative of the marketing authorization holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
Oral use.

Dosage:
The recommended dosage is 200 mcg/kg bw of ivermectin and 1 mg/kg bw of praziquantel corresponding to 1.29 g of paste per 100 kg bodyweight in a single administration.
Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg, calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger.

Parasite control Program: Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
To ensure a correct dosage, body weight should be determined as accurately as possible.
While holding the plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the stop ring is at the prescribed weight marking. Lock the ring in place by turning it ¼ turn to the right in order to bring the two arrows, the one visible on the ring and the one on the plunger rod, into alignment. Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing and ensure that the paste is consumed.

11. WITHDRAWAL PERIODS

Withdrawal periods
Meat and offal: 30 days.
Not authorised for use in animal producing milk for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions
Keep out of the sight and reach of children.
Store in the original container.
Replace the cap after use.
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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water course as ivermectin and praziquantel may be dangerous for fish and other aquatic organisms.

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. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

To be completed nationally

Pack sizes
Carton box of 1 syringe for oral administration of 7.74g
Carton box of 1 syringe for oral administration of 9.68g
Carton box of 1 syringe for oral administration of 14.19g
Carton box of 50 syringes for oral administration of 7.74g
Carton box of 50 syringes for oral administration of 9.68g
Carton box of 50 syringes for oral administration of 14.19g

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised
{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details
Marketing authorisation holder and contact details to report suspected adverse reaction:
To be completed nationally.

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

18. OTHER INFORMATION

Other information
Environmental properties
EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp.: {month/year}
Once opened, use within 2 years

21. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQVALAN DUO

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ivermectin 15.5 mg/g
Praziquantel 77.5 mg/g

7.74 g
9.68 g
14.19 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {month/year}
Once opened use by…..

B. PACKAGE LEAFLET

PACKAGE LEAFLET

The leaflet described below applies to Case N°1 where a package leaflet is added in the packaging. In Case N°2 no leaflet is needed.

1. Name of the veterinary medicinal product

EQVALAN DUO, oral paste

2. Composition

Each g contains:

Active substances:
Ivermectin.....15.5 mg
Praziquantel.....77.5 mg

Excipients:
Titanium dioxide (E171) ..... 20 mg
Sunset Yellow (E110) .....0.40 mg
Buthylhydroxyanisole (E320) .....0.20 mg

Smooth, homogeneous orange paste.

3. Target species

Horses.

4. Indications for use

For the treatment of mixed cestode and nematode or arthropod infestations in horses. The following parasites of horses are sensitive to the antiparasitic effects of the veterinary medicinal product:

Adult Tapeworms:
Anoplocephala perfoliata
Anoplocephala magna

Large strongyles:
Strongylus vulgaris (adults and arterial larval stages)
Strongylus edentatus (adults and tissue larval stages)
Strongylus equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus
Craterostomum acuticaudatum (adults)

Adult and immature (intraluminal fourth-stage larvae) of small strongyles or cyathostomes, including benzimidazole-resistant strains:

Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus
Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum
Cylicocyclus spp.
Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
Cylicostephanus spp.
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Parapoteriostomum spp.
Parapoteriostomum mettami
Petrovinema spp.
Petrovinema poculatum
Poteriostomum spp.

Adult hairworms: *Trichostrongylus axei*
Adult and immature (fourth stage Larvae) pinworms: *Oxyuris equi*
Adult, third- and fourth-stage larvae of roundworms (ascarids): *Parascaris equorum*
Microfilariae of neck threadworms: *Onchocerca* spp.
Adult intestinal threadworms: *Strongyloides westeri*
Adult large-mouth stomach worms: *Habronema muscae*
Oral and, gastric stages of bots: *Gasterophilus* spp.
Adult and immature (inhibited fourth stage larvae) lungworms: *Dictyocaulus arnfieldi*

5. Contraindications

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.

6. Special warnings

Special warnings:
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, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device (if any).

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.
Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of gastro-intestinal nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
Safety studies were not conducted in foals younger than 2 months of age, or in stallions, the use of the veterinary medicinal product is not recommended in these categories of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Do not smoke, drink or eat while handling the veterinary medicinal product.
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 insert or the label to the physician.

Pregnancy and lactation:
Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of either ivermectin or praziquantel at the recommended doses during therapy.

Ivermectin-Praziquantel combination can be used after the first three months of gestation and during lactation. In the absence of clinical data in early pregnancy the veterinary medicinal product can only be used in the first three months of gestation according to a risk benefit analysis by the veterinarian.

Overdose:
No undesirable effects related to treatment were observed in 2-month-old horses treated with the veterinary medicinal product at up to three times the recommended dose and in adult horses treated at ten times the recommended dose.

Transient decreased food consumption, increased body temperature, salivation and impairment of vision were noticed in horses treated twice with an ivermectin oral paste or once with the veterinary medicinal product at ten times the recommended dose (i.e., 2 mg/kg b.w.). All changes disappeared within five days.

No antidote has been identified; however, symptomatic therapy may be beneficial.

7. Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):
Oedema[1]
Pruritis[1]
Inflammation of the mouth, lip and tongue (e.g.,lip erythema, lip oedema, tongue oedema, tongue inflammation, tongue disorders, stomatitis, hypersalivation)[2].

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Abdominal discomfort (colic, loose stool).

[1] Can occur in some horses with heavy infections of *Onchocerca Spp. microfilariae* following treatment; such reactions were assumed to be the result of the death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.
[2]These reactions have been transitory in nature, appearing within 1 hour and abating within 24 to 48 hours following administration. In case of severe oral reactions symptomatic treatment is recommended.

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 authorization holder or its local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Oral use.

The recommended dosage is 200 mcg/kg bw of ivermectin and 1 mg/kg bw of praziquantel corresponding to 1.29 g of paste per 100 kg bodyweight in a single administration.
Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg, calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger.

Parasite control Program:
Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

While holding the plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the stop ring is at the prescribed weight marking. Lock the ring in place by turning it ¼ turn to the right in order to bring the two arrows, the one visible on the ring and the one on the plunger rod, into alignment. Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing and ensure that the paste is consumed.

10. Withdrawal periods

Meat and offal: 30 days.
Not authorised for use in animal producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.
Replace cap after use.
Shelf life after first opening the immediate packaging: 2 years
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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water course as ivermectin and praziquantel may be dangerous for fish and other aquatic organisms.

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. 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 number and pack sizes

To be completed nationally.

Outer package and sales presentations:
Each syringe is sealed in a transparent polypropylene bag.

Carton box of 1 syringe for oral administration of 7.74g
Carton box of 1 syringe for oral administration of 9.68g
Carton box of 1 syringe for oral administration of 14.19g
Carton box of 50 syringes for oral administration of 7.74g
Carton box of 50 syringes for oral administration of 9.68g
Carton box of 50 syringes for oral administration of 14.19g

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 contact details to report suspected adverse reaction:
To be completed nationally.

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

17. Other information

Environmental properties
EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE.