ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Z-Itch 40 mg/ml Pour-on Solution
Permethrin (80:20)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 40 mg permethrin (80:20)

3. PHARMACEUTICAL FORM

Pour-on solution.

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Horses and donkeys

6. INDICATION(S)

For OTC products:
For use as an aid in the control of sweet itch due to its repellent effect on the biting insect *Culicoides* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For OTC products:
The product is a ready-to-use, pour-on solution which should be administered at the rate of 4 mg/kg bodyweight, equivalent to 1.0 ml per 10 kg bodyweight to a maximum of 40 ml.

Dosage guidelines

Body weight (kg)	100	200	250	300	>400
Dose volume (ml)	10	20	25	30	40

Application
Apply the measured dose in approximately equal proportions to the mane and rump avoiding the saddle area. Treatment should be started at the beginning of the sweet itch season. Treatment once weekly should be sufficient for most horses and donkeys.

If horses and donkeys are to be groomed, apply the product after grooming.
The product must not be applied forward of the ears. Take care to avoid eye contact.
In case of accidental splashing into the animal's eye, the affected eye should be washed thoroughly and immediately with copious quantities of clean water and veterinary attention sought.

Read the package leaflet before use.

For medical prescription products:
Read the package leaflet before use.
Pour-on use.

8. WITHDRAWAL PERIOD(S)

Not authorised for use in horses or donkeys intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

User warnings
The product may cause neurotoxic effects and skin and eye irritation.
Personal protective equipment consisting of protective clothing, boots and chemically resistant gloves such as rubber, PVC or nitrile should be worn when handling the veterinary medicinal product. In case of accidental spillage onto skin or into eyes rinse immediately with water.
Wash hands after use.
Use in a well ventilated area.
Ensure that the treated area is dry before allowing skin contact with the treated animal.
In case of accidental exposure seek medical advice and show the package leaflet or the label to the physician.
Keep away from food, drink and animal feeding stuffs.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original container.
Keep the bottle tightly closed and store it in a dry place in order to protect from moisture.
Keep the bottle in the outer carton to protect from light.

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

Disposal
The product may adversely affect aquatic organisms and bees. Do not contaminate ponds, waterways or ditches with the product or used container.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

For animal treatment only.

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

Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 56190/5000

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Z-Itch 40 mg/ml Pour-on Solution
Permethrin (80:20)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 40 mg permethrin (80-20)

3. PHARMACEUTICAL FORM

Pour-on solution.

4. PACKAGE SIZE

250ml

5. TARGET SPECIES

Horses and donkeys

6. INDICATION(S)

For OTC products:
For use as an aid in the control of sweet itch due to its repellent effect on the biting insect *Culicoides* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For OTC products:
The product is a ready to use pour-on solution administered at the rate of 4 mg/kg bodyweight, equivalent to 1.0 ml per 10 kg bodyweight to a maximum of 40 ml.
For dosage guidelines and application instructions read the package leaflet before use.

For medical prescription products:
Read the package leaflet before use. Pour-on use.

8. WITHDRAWAL PERIOD(S)

Not authorised for use in horses or donkeys intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

User warnings
The product may cause neurotoxic effects and skin and eye irritation.
Personal protective equipment consisting of protective clothing, boots and chemically resistant gloves such as rubber, PVC or nitrile should be worn when handling the veterinary medicinal product. In case of accidental spillage onto skin or into eyes rinse immediately with water.
Wash hands after use.
Use in a well-ventilated area.
Ensure that the treated area is dry before allowing skin contact with the treated animal.

In case of accidental exposure seek medical advice and show the package leaflet or the label to the physician.
Keep away from food, drink and animal feeding-stuffs.

For the full product warnings read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original container. Keep the bottle tightly closed and store it in a dry place in order to protect from moisture.
Keep the bottle in the outer carton in order to protect from light.

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

For disposal advice read the package leaflet before use.

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

For animal treatment only.

UK: AVM-GSL

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

Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 56190/5000

17. MANUFACTURER'S BATCH NUMBER

BN:

Distributor:
Trilanco Ltd.
Coronation Way
Mill Farm Sports Village
Wesham, Preston
PR4 3JZ
t: 01772 754810

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Z-Itch 40 mg/ml Pour-on Solution

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

Marketing authorisation holder:
Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

Manufacturer responsible for batch release:
Floris Veterinaire Produkten BV
Kempenlandstraat 33
5262 GK Vught
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Z-Itch 40 mg/ml Pour-on Solution
Permethrin (80:20)

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

The product is a clear, colourless to pale yellow, non-aqueous solution.
Each ml contains:

Permethrin(80:20) 40 mg

4. INDICATION(S)

For use as an aid in the control of sweet itch due to its repellent effect on the biting insect *Culicoides* spp.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in equids suffering from hepatic disease.
Do not use in cats.

6. ADVERSE REACTIONS

A few horses, particularly those of the fine-skinned Arab type, may react adversely to treatment with the product. In such individuals a small patch test at the base of the

neck is recommended. If adverse reactions should occur, treatment should be stopped immediately. Any resulting skin irritation is short lived.

Procedure for patch testing
Using protective gloves apply a small quantity of the product (about 1 ml) to an identifiable area at the base of the animal's neck and rub onto the skin with a swab. Wrap the used swab in the gloves and dispose of safely. At 24 and 48 hours after application, examine the area to which the product was applied and observe the skin for signs of reaction (redness, swelling, flaking or exudation). If a reaction occurs, do not use the product on the animal.

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 {national system details}.

7. TARGET SPECIES

Horses and donkeys.

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

The product is a ready-to-use, pour-on solution which should be administered at the rate of 4 mg/kg bodyweight, equivalent to 1.0 ml per 10 kg bodyweight to a maximum of 40 ml.

Dosage guidelines

Bodyweight (kg)	100	200	250	300	> 400
Dose volume (ml)	10	20	25	30	40

9. ADVICE ON CORRECT ADMINISTRATION

Application

Apply the measured dose in approximately equal proportions to the mane and rump avoiding the saddle area. Treatment should be started at the beginning of the sweet itch season. Treatment once weekly should be sufficient for most horses.

If horses and donkeys are to be groomed, apply the product after grooming.

10. WITHDRAWAL PERIOD

Not authorised for use in horses or donkeys intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in the original container. Keep the bottle tightly closed and store it in a dry place in order to protect from moisture.
Keep the bottle in the outer carton in order to protect from light.
Keep out of sight and reach of children.
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 WARNING(S)

For animal treatment only.

Special warnings for each target species

Sweet itch is believed to be caused by hypersensitivity to the bites of flying insects e.g. *Culicoides* species. In addition to treatment, other measures should be taken to reduce exposure to such insects where practicable. It may be appropriate for owners to seek veterinary advice on management of horses with sweet itch. It is also recommended that owners seek veterinary advice in severe cases of sweet itch and in cases of sweet itch which do not respond to treatment. Washing or exposure to rain after application of the product may affect protection.
Do not treat the saddle area.

Special precautions for use in animals

For external use only.
The product must not be applied forward of the ears.
Take care to avoid eye contact.
In case of accidental splashing into the animal's eye, the affected eye should be washed thoroughly and immediately with copious quantities of clean water and veterinary attention sought.

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

The product may cause neurotoxic effects and skin and eye irritation.
Personal protective equipment consisting of protective clothing, boots and chemically resistant gloves such as rubber, PVC or nitrile should be worn when handling the veterinary medicinal product. In case of accidental spillage onto skin or into eyes rinse immediately with water
Wash hands after use.
Use in a well-ventilated area.

Ensure that the treated area is dry before allowing skin contact with the treated animal.
In case of accidental exposure seek medical advice and show the package leaflet or the label to the physician.
Keep away from food, drink and animal feeding stuffs.

Pregnancy, Lactation, Fertility

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

Care should be taken when applying the product as it may have an adverse effect on certain plastics.
The product could prolong the effect of barbiturates.

Overdose (symptoms, emergency procedures, antidotes)

Toxic signs in equidae are tremors, hyperexcitability, salivation, choreoathetosis and paralysis. The signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if considered necessary.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
The product could prolong the effect of barbiturates.

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

Disposal advice
The product may adversely affect aquatic organisms and bees. Do not contaminate ponds, waterways or ditches with the product or used container.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

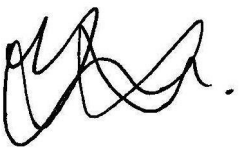
15. OTHER INFORMATION

Package quantities
250 ml high density polyethylene container with white polypropylene screw cap.

Marketing Authorisation number
UK: Vm 56190/5000

UK legal category: AVM-GSL

Distributor:
Trilanco Ltd.
Coronation Way
Mill Farm Sports Village
Wesham, Preston
PR4 3JZ
t: 01772 754810



Approved: 19 October 2023