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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 40 mg permethrin (80:20)

3. PACKAGE SIZE

250 ml

4. TARGET SPECIES

Horses and donkeys

5. INDICATIONS

For products not subject to veterinary prescription:
For use as an aid in the control of sweet itch due to its repellent effect on the biting insect *Culicoides*
spp.

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. 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.

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

Floris Holding B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 56190/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Z-Itch 40 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 40 mg permethrin (80-20)

3. TARGET SPECIES

Horses and donkeys

4. ROUTES OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}

7. 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Floris Holding B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Z-Itch 40 mg/ml pour-on solution

2. Composition

Each ml contains:

Active substance:
Permethrin (80:20) 40 mg

A clear, colourless to pale yellow, non-aqueous pour-on solution.

3. Target species

Horses and donkeys.

4. Indications for use

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 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. Special warnings

Special warnings:
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 veterinary medicinal product may affect protection.

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

Special precautions for safe use in the target species:
For external use only.
The veterinary medicinal 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.
Do not treat the saddle area.

Procedure for patch testing:
Using protective gloves apply a small quantity of the veterinary medicinal 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 veterinary medicinal product was applied and observe the skin for signs of reaction (redness, swelling, flaking or exudation).

If a reaction occurs after the patch testing, do not use the veterinary medicinal product on the animal.
If adverse reactions should occur, treatment should be stopped immediately.
Any resulting skin irritation is short lived.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal 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 immediately and show the package leaflet or the label to the physician. Keep away from food, drink and animal feeding stuffs.

People with known hypersensitivity to permethrin should avoid contact with the veterinary medicinal
product.

Special precautions for the protection of the environment:
The veterinary medicinal product may adversely affect aquatic organisms and bees.
Do not contaminate ponds, waterways or ditches with the product or used container.

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

Interaction with other medicinal products and other forms of interaction:
Care should be taken when applying the veterinary medicinal product as it may have an adverse effect on certain plastics. The veterinary medicinal product could prolong the effect of barbiturates.

Overdose:
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.

Special restrictions for use and special conditions for use:
Not applicable.

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 and donkeys:

Undetermined frequency (frequency cannot be estimated from the available data):
Application site reaction[1], Application site irritation[1], Application site hair loss[1], Application site alopecia[1]

[1] A few horses, particularly those of the fine-skinned Arab type, may present signs of skin irritation or hypersensitivity to treatment with the veterinary medicinal product. In such individuals, a small patch test at the base of the neck 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 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

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

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 veterinary medicinal product after grooming.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

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.

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.
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.

The veterinary medicinal product should not enter water courses as permethrin may be dangerous for fish and other aquatic organisms.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

UK (NI): Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box with 250 ml HDPE bottle closed with a screw fit cap and an integral graduated dispensing chamber as dosing device.

15. Date on which the package leaflet was last revised

December 2022

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 reactions:
Floris Holding BV
Kempenlandstraat 33
5262 GK Vught
The Netherlands
+31(0)73 656 76 47
pharmacovigilance@florispharma.com

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

17. Other information

Approved 20 April 2023