SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Z-Itch 40 mg/ml pour-on solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Permethrin (80:20) 40 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butyl dioxitol	

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

3. CLINICAL INFORMATION

3.1 Target species

Horses and donkeys.

3.2 Indications for use for each target species

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

3.3 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.

3.4 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 SPC 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.

3.5 Special precautions for use

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.
See also section 3.6.

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.

3.6 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 (see section 3.5).

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 the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Pour-on use.

Horses and donkeys: 4 mg/kg body weight, 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

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AC04

4.2 Pharmacodynamics

Permethrin belongs to the Type I class of pyrethroids with repellent activity. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so-called 'open channel blockers' affecting the sodium channel by slowing both the activation and the inactivation properties, thus leading to hyper-excitability and death of the parasite.

4.3 Pharmacokinetics

The veterinary medicinal product is indicated for cutaneous administration. Following topical application, the solution is distributed over the skin.

Synthetic pyrethroids are generally metabolised in mammals through ester hydrolysis, oxidation and conjugation, and there is no tendency for tissue accumulation. Permethrin is classified as a photostable synthetic pyrethroid, and acts topically.

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: 2 years.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Natural, high density polyethylene bottle closed with a white, polypropylene screw fit cap with induction seal in a cardboard box. The bottle incudes an integral graduated dispensing chamber as dosing device.

Pack sizes:
Bottle containing 250 ml.

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.

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.

The veterinary medicinal product should not enter water courses as permethrin may be dangerous for fish and other aquatic organisms.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Floris Holding B.V.
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 56190/3000

8. DATE OF FIRST AUTHORISATION

27 January 2011

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

April 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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

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

Approved 20 April 2023