Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Z-Itch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Permethrin (80:20) technical 40.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and donkeys.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 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.

4.5 Special precautions for use

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.
Do not treat the saddle area.
See also section 4.6.

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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 product after grooming.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl insecticides, permethrin

ATCvet code: QP53AC04.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

The 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butyl dioxitol.

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 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.

6.5 Nature and composition of immediate packaging

Container size: 250 ml.

Container material: Natural, high density polyethylene bottle in a cardboard box.

Closure: White, polypropylene screw fit cap with induction seal.

Dosing device: Integral graduated dispensing chamber.

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

The product may adversely affect aquatic organisms and bees. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Floris Holding BV
Kempenlandstraat 33
5262 GK Vught
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA22969/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 June 2013
Date of last renewal: 13 January 2017

10 DATE OF REVISION OF THE TEXT

February 2020