SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Switch 4% w/v Pour-on Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Qualitative composition</u> Permethrin (cis trans 80:20) Quantitative composition 4.0% w/v

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Pour-on Solution

Switch is a clear, colourless to pale yellow liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and donkeys

4.2 Indications for use, specifying the target species

As an aid in the control of sweet itch on horses and donkeys

4.3 Contraindications

Do not treat the saddle area.

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 spp*. It may be appropriate for owners to seek veterinary advice in severe cases of sweet itch, and in cases of sweet itch which do not respond to treatment.

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.

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.

Take care to avoid eye contact. The product must not be applied forward

of the ears. In case of accidental splashing in to the horse's eye, the affected eye should be washed thoroughly and immediately with copious quantities of clean water and veterinary attention sought.

ii. Special precautions for the person administering the veterinary medicinal product to animals

The product may cause neurotoxic effects and skin and eye irritation.

Wear protective clothing, boots and chemically resistant gloves such as rubber, PVC or nitrile when applying the product.

Wash splashes from the skin and eyes immediately.

If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

When using the product do not eat, drink or smoke. Wash hands and exposed skin before eating, drinking or smoking.

Use in a well ventilated area.

Keep away from food, drink and animal feedstuffs.

iii. Other precautions

For external use only.

4.6 Adverse reactions (frequency and seriousness)

See section 4.5 i.

4.7 Use during pregnancy, lactation or lay

No special precautions required.

4.8 Interaction with other medicinal products and other forms of interaction

Care should be taken when applying this product, as it may have an adverse effect on certain plastics.

4.9 Amount(s) to be administered and administration route

Horses and donkeys 1ml per 10 kg body weight up to a maximum of 40 ml on horses and donkeys.

Apply the measured dose in approximately equal portions to the mane and rump avoiding the saddle area. Treatment should be started at the start of the sweet itch season and should be repeated as necessary – treatment once weekly should be sufficient for most horses.

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

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

Toxic signs in mammals 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 to be used in horses and donkeys intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Anti-parasitic products (Permethrin)

ATC Vet Code:

QP53AC04

5.1 Pharmacodynamic properties

Permethrin is a neuropoison acting on the axons in the peripheral and central nervous system by interacting with the sodium channels in insects. Synthetic pyrethroids are generally metabolised in mammals through ester hydrolysis, oxidation and conjugation and there is no tendency to accumulate in tissues.

5.2 Pharmacokinetic properties

Permethrin is classified as a photostable synthetic pyrethroid, and acts topically.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butyl dioxitol

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in tightly closed original container. Do not store above 25°C

6.5 Nature and composition of immediate packaging

250ml natural high density polyethene (HDP) bottles, with integrated graduated dispensing chamber. Closure is a white opaque urea formaldehyde screw fit cap.

Each bottle of Switch is supplied in a cardboard carton directly on to which are coloured printed product details.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

7 MARKETING AUTHORISATION HOLDER

VetPlus Ltd Animal House Boundary Road Lytham Lancashire FY8 5LT

8. MARKETING AUTHORISATION NUMBER

Vm 18182/4000

9. DATE OF FIRST AUTHORISATION

21 November 1994

10. DATE OF REVISION OF THE TEXT

March 2023

Approved: 17 March 2023