

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Killitch 25% w/v cutaneous emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition Quantitative composition

Active substance: Benzyl 25.0% w/v
Benzoate

Other ingredients: 0.05% w/v
Bronopol

See section 6.1 for list of
excipients

3. PHARMACEUTICAL FORM

Cutaneous emulsion

This product is a creamy white, viscous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and ponies

4.2 Indications for use, specifying the target species

For the treatment of "Sweet Itch" in horses

4.3 Contraindications

Avoid contact with eyes and mucous membranes.

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 the initial treatment.

4.5 Special precautions for use

i. Special precautions for use in animals

Avoid contact with eyes and mucous membranes. For external use only.

- Special precautions for the person administering the veterinary medicinal product to animals

Protective rubber gloves should be worn when using this product. Using this product may cause skin irritation in sensitive individuals. Wash hands thoroughly after use. In case of eye or skin contact wash the affected areas immediately with plenty of water. If irritation occurs, seek medical advice showing the product label.

HARMFUL IF SWALLOWED. DO NOT INDUCE VOMITING – seek medical attention, showing the product label to a doctor or nurse. Do not eat, drink or smoke while using this product.

4.6 Adverse reactions (frequency and seriousness)

Very occasionally, this product *may* result in a mild skin reaction, characterised by swelling, heat and/ or hair loss. If this occurs, any remaining product should be thoroughly washed off, product use discontinued, and veterinary attention sought.

4.7 Use during pregnancy, lactation or lay

No specific studies have been conducted in pregnant or lactating horses.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amount(s) to be administered and administration route

For topical administration. Shake bottle before use. Wear protective gloves. Apply to all affected areas by rubbing in with fingers or a clean soft cloth immediately if Sweet Itch is diagnosed. All affected areas should be kept clean by shampooing and rinsing well at least once a week. Initially application of the treatment should be made twice daily, reducing to once daily and 3-4 times a week, as the irritation lessens. An initial application of around 75ml should be made to the mane, tail and rump areas and other effected areas. Top this up as required with doses of around 25ml. After shampooing or heavy exercise, an application of around 75ml should be made to ensure adequate protection. With animals, which are known to suffer from Sweet Itch, it is recommended that the treatment be applied in early spring before symptoms become evident, so that the condition may never take hold.

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

Signs of excess application include nervous effects. Administration should be stopped and only resumed at a lower usage rate.

4.11 Withdrawal period(s)

Not to be used on horses 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:

Ectoparasiticide for topical use

ATC Vet Code:

QP53AX11

5.1 Pharmacodynamic properties

The mechanism of action is unknown.

5.2 Pharmacokinetic properties

Not known. The product acts topically.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bronopol
Emulsifying wax
Water potable

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Store in tightly closed original container.
Do not store above 25°C.
Protect from frost.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

500ml and 1 litre white opaque high density polyethylene bottles and 2.5 litre blue opaque high density polyethylene jerricans. White opaque polypropylene, child resistant screw fit caps.
Not all pack sizes may be marketed.

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.

7 MARKETING AUTHORISATION HOLDER

Carr Day and Martin Limited
Boundary Road
Lytham

8. MARKETING AUTHORISATION NUMBER(S)

Vm 01974/4003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date: 24th June 1995/ 24th June 2005

10. DATE OF REVISION OF THE TEXT

Date: 06th March 2008