

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coopers Fly Repellent Plus 1.05% Cutaneous Emulsion for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	%w/v
Permethrin (cis:trans 25:75) technical	1.05
to provide permethrin (cis:trans 25:75) pure	1.00
Citronellol	2.00

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous emulsion.

4. CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

As a ready-to-use, topical application to repel and kill biting and other flies on horses; as an aid in the control of sweet itch, a condition believed to be caused by the midge *Culicoides pulicaris*.

For the treatment and control of infestations of the biting louse, *Damalinia equi*. Also shines horses' coats.

4.3 Contra-indications

Do not use with other topically applied products.

Avoid application into the horse's eyes and nostrils or into cuts and abrasions.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

- i) Special precautions for use in animals
None

- ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid prolonged contact with the skin.

Impervious gloves should be worn when applying this product.

Wash hands and exposed skin before meals or smoking and after work.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

A small proportion of horses may exhibit a skin reaction following application of the product. This reaction is normally mild and transient, resembling nettle-rash and usually resolves without the need for any treatment.

Application to a small area on the side of the neck, before the first occasion of use, should determine within 24 hours whether such a reaction is likely.

4.7 Use during pregnancy, lactation or lay

The product may be used on pregnant and lactating animals. Due regard must always be given to physical condition, particularly of any animals in advanced pregnancy, and/or under stress from adverse weather conditions, poor nutrition, handling etc.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use with other topically applied products.

4.9 Amounts to be administered and administration route

Shake the product thoroughly before use. No dilution is necessary.

Apply shortly before working the horse or when flies are troublesome, at the following rate:

Bodyweight	Dose
Up to 300 kg	100 ml
301 - 500 kg	150 ml
Over 500 kg	up to 200 ml

If the horse is to be groomed, the product should not be applied until after this has been completed.

Pour the product onto the sponge cloth and spread lightly over the horse's head, neck, body and legs measuring the dose volume against the calibrations on the 600 ml container.

Fly control: Where flies appear to be troublesome only around the horse's head and neck a reduced amount may be applied to these parts alone.

Repeat every other day or as necessary.

A treatment will normally give two to four days relief, but longer or shorter protection may occur depending on climatic conditions, the prevailing fly species and the intensity of fly worry.

Louse control: A single application of Coopers Fly Repellent Plus will usually eliminate adult populations of the biting louse *Damalinia equi*, and viable eggs for up to 3 months. However, as this protection is not absolute, it is advisable to repeat treatment after an interval of 14 days. Ensure that the whole body is treated including the head and the tail.

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

Horses treated with 3 x recommended therapeutic dose showed no signs of clinical toxicity or irritation.

4.11 Withdrawal Period

Not to be used on horses 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 the national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Permethrin, like other synthetic pyrethroids, is a neuropoison acting on the axons in the peripheral and central nervous system by interacting with sodium channels. Permethrin is a residual insecticide with a contact repellent and killing action. It is a highly effective insecticide of extremely low mammalian toxicity. The 25: 75 cis:trans isomer ratio is the least toxic form of permethrin available.

Permethrin is readily metabolised by man and animals, and is more potently toxic to ectoparasitic arthropods such as flies and lice because of the much slower rate of metabolism and elimination of the chemical by the ectoparasites.

Citronellol (3,7-dimethyl -6-octen-1-ol) is a well recognised ingredient of perfumed cosmetics and is defined as a safe flavouring substance. It also possesses good fly repellent properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nonyl Phenol Ethoxylate 9.5 mole
Silica in Dimethicone
Water (Purified)

6.2 Incompatibilities

None described.

6.3 Shelf life

Shelf-life of the product as packaged for sale: 4 years.

6.4 Special precautions for storage

Do not store above 25°C.

Store away from food, drink and animal feedingstuffs.

Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

Size: 600 ml.

Container: Unpigmented high density polyethylene bottle with internal graduated measuring chamber.

Closures: White polypropylene screw cap with induction seal liner.

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

Dangerous to fish and crustaceans. 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4596

9. DATE OF FIRST AUTHORISATION

6 May 1986

10. DATE OF REVISION OF THE TEXT

April 2021

Approved: 28/04/21