PARTICULARS TO APPEAR ON THE OUTER PACKAGE & IMMEDIATE PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coopers Fly Repellent Plus 1.05% Cutaneous Emulsion for Horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Cutaneous emulsion.

Wipe-on lotion.

4. PACKAGE SIZE

600 ml

5. TARGET SPECIES

Horse

6. INDICATION(S)

Repels and kills biting and other Flies

Controls biting Lice

Aids in the control of Sweet Itch

Indications

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 Culiciodes pulicaris.

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.

Read instructions before use.

SHAKE THE PRODUCT THOROUGHLY BEFORE USE.

Dosage and administration

No dilution is necessary.

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

Up to 300 kg bodyweight: 100 ml

301 - 500 kg bodyweight: 150 ml

Over 500 kg bodyweight: up to 200 ml

Fly control:



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



2. Wearing the glove provided, pour the product onto the sponge cloth, measuring the dose volume against the calibrations on the container.



3. Spread lightly over the horse's head, neck, body and legs measuring the dose volume against the calibrations on the 600 ml container.



4. 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.

<u>Louse control:</u> 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.

8. WITHDRAWAL PERIOD

Included in Contra-indications and warnings section

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.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications and warnings

Do not use with other topically applied products. Avoid application into the horse's eyes and nostrils or into cuts and abrasions.

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.

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.

If signs of disease persist or appear consult your veterinary surgeon.

Do not use with other topically applied products.

Operator warnings:

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.

10. EXPIRY DATE

EXP end of:

11. SPECIAL STORAGE CONDITIONS

Storage and disposal advice

Do not store above 25°C.

Store away from food, drink and animal feedingstuffs.

Store in tightly closed original container.

Dangerous to fish and crustaceans. Do not contaminate ponds, waterways or ditches with the product or used containers.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Included in Storage and disposal advice section

Dispose of used sponges, empty containers and any unused product in the household refuse.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

For animal treatment only.

AVM-GSL

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder

MSD Animal Health UK Ltd. Walton Manor Walton Milton Keynes MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4596

17. MANUFACTURER'S BATCH NUMBER

Batch no.

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET,

BOTTLE LABEL

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

Manufacturer responsible for batch release:

Schering – Plough Animal Health Breakspear Road Harefield Uxbridge Middlesex UB9 6LS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coopers Fly Repellent Plus 1.05% Cutaneous Emulsion for Horses

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

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

4. PHARMACEUTICAL FORM

Cutaneous emulsion.

Wipe-on lotion.

5. PACKAGE SIZE

600 ml

6. INDICATION(S)

Indications

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 Culiciodes pulicaris.

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

7. CONTRAINDICATIONS

Contra-indications and warnings

Do not use with other topically applied products. Avoid application into the horse's eyes and nostrils or into cuts and abrasions.

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.

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.

If signs of disease persist or appear consult your veterinary surgeon.

Do not use with other topically applied products.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Horse

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and administration

No dilution is necessary.

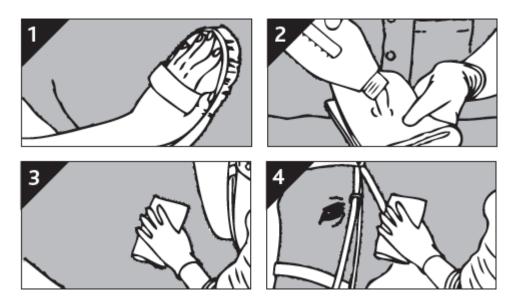
Apply shortly before working the horse or when flies are troublesome, at the following rate:

Up to 300 kg bodyweight: 100 ml

301 - 500 kg bodyweight: 150 ml

Over 500 kg bodyweight: up to 200 ml

Fly control:



- 1. If the horse is to be groomed, the product should not be applied until after this has been completed.
- 2. Wearing the glove provided, pour the product onto the sponge cloth, measuring the dose volume against the calibrations on the container.
- 3. Spread lightly over the horse's head, neck, body and legs measuring the dose volume against the calibrations on the 600 ml container.
- 4. 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.

<u>Louse control:</u> 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.

11. ADVICE ON CORRECT ADMINISTRATION

SHAKE THE PRODUCT THOROUGHLY BEFORE USE.

For external use only.

Read instructions before use.

12. WITHDRAWAL PERIOD

Included in Contra-indications and warnings section

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.

13. SPECIAL STORAGE PRECAUTIONS

Storage and disposal advice

Do not store above 25°C.

Store away from food, drink and animal feedingstuffs.

Store in tightly closed original container.

Dangerous to fish and crustaceans. Do not contaminate ponds, waterways or ditches with the product or used containers.

14. SPECIAL WARNING(S)

Operator warnings:

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.

15. EXPIRY DATE

EXP end of:

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Included in Storage and disposal advice section

Dispose of used sponges, empty containers and any unused product in the household refuse.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

April 2021

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

AVM-GSL

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4596

21. MANUFACTURER'S BATCH NUMBER

Batch no.

Approved: 28/04/21

D. Austur