

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flypor 4% w/v Pour-on Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>% w/v</u>
Permethrin tech. (cis:trans 80:20)	4.0

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on Solution.
Clear, straw coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For the control of flies (particularly biting flies and horn-flies) and lice (including sucking and biting lice), and for the treatment of sarcoptic and chorioptic mange of cattle.

4.3 Contraindications

Do not treat calves under one week old.

4.4 Special warnings for each target species

As with all insecticides, the degree of fly-killing and repellent activity afforded by the product is influenced by prevailing weather conditions and the species of flies involved.

For external use only.

4.5 Special precautions for use

- i) Special precautions for use in animals

Avoid the eyes when applying to the head.

- ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wear protective clothing, rubber gloves and boots when applying the product.

Avoid contact with the eyes. If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

Do not eat, drink or smoke whilst using the product.

Wash hands and exposed skin before eating, drinking or smoking and after work.

Use in a well-ventilated area. Do not inhale the vapour.

- iii) Other precautions

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

The products must be applied only with the Elanco Cattle Pour-On Gun as the product may have a detrimental effect on certain components of conventional dosing guns.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy.

Use only according to the benefit/risk assessment of the responsible veterinary surgeon.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Flypor is a ready-to-use solution which should be applied at the rate of 1 ml per 10 kg bodyweight up to a maximum of 40 ml.

<u>Bodyweight</u>	<u>Dose</u>
Calves up to 100 kg	10 ml
101 to 200 kg	20 ml
201 to 300 kg	30 ml
Over 300 kg	40 ml

The product should be applied using either the calibrated dispensing chamber incorporated into the applicator bottle, or the flexi-pack with a Elanco Cattle Pour-On Gun.

Flies: Apply approximately one quarter of the calculated dose to the top of the head; the remainder should be poured along the neck and mid-backline. A single dose is normally sufficient to control flies for up to 8 weeks. The first treatment should be carried out when the number of flies start to increase. In cases of heavy infestation, the dose may be repeated at 4 week intervals.

Lice: Apply in the same way as fly dosage. A single dose is normally sufficient to control all lice. In certain cases of heavy infestation, the dose may be repeated after 4 weeks.

Sarcoptic and chorioptic mange: The calculated dose should be applied directly to all visibly affected areas; any remaining should be poured along the backline in the normal way. The dose should be repeated after 4 weeks.

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

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis 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)

Meat: Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 3 days from the last treatment.

Milk: Cattle producing milk for human consumption should be treated immediately after milking to allow as long an interval as possible (at least 6 hours) before the next milking. There is no need to withhold milk from subsequent milkings.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use

ATC Vet code: QP53AC04

5.1 Pharmacodynamic properties

Permethrin is a neurotoxin acting on the axons in the peripheral and central nervous system by interacting with sodium channels in insects. *In vitro* data obtained using hair from treated animals has demonstrated that the product has the potential to be effective against *Culicoides* biting midges, although this has not been confirmed by clinical trials.

5.2 Pharmacokinetic particulars

Synthetic pyrethroids are generally metabolized in mammals through ester hydrolysis, oxidation and conjugation and there is no tendency to accumulate in tissues.

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.
Store away from food, drink and animal feedstuffs.

6.5 Nature and composition of immediate packaging

250 ml, 500 ml & 1 litre pack	A natural, high density polyethylene bottle with integral graduated dispensing chamber, closed with a white, urea screw cap and foil induction seal.
1, 2, 2.5, 3, 4 & 5 litre flexi-pack	A white, opaque, high density polyethylene flex-pack closed with a white, polypropylene screw cap and foil induction seal.

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

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 aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4008

9. DATE OF FIRST AUTHORISATION

11 April 1995

10. DATE OF REVISION OF THE TEXT

September 2020

A handwritten signature in black ink, consisting of several stylized, overlapping loops and a long, sweeping tail that curves downwards and to the right.

Approved 09 September 2020