PACKAGE LEAFLET
INTERCEPTOR PLUS/ PROGRAM Plus

Please note that for some countries, the same package leaflet is common to all dosage strengths/pack sizes. In other countries there is a package leaflet per dosage strength as not all dosage strengths might be marketed.

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

Marketing Authorisation Holder:
Elanco Europe Ltd
Lilly House
Priestly Road
Basingstoke
Hampshire
RG24 9NL

Manufacturer responsible for batch release: Elanco France S.A.S., 26 Rue de la Chapelle, F-68330 Huningue, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRAM Plus

Other names in different Member States:
UK: PROGRAM Plus film-coated tablets 2.3 mg/46 mg
UK: PROGRAM Plus film-coated tablets 5.75 mg/115 mg
UK: PROGRAM Plus film-coated tablets 11.5mg/230 mg
UK: PROGRAM Plus film-coated tablets 23 mg/460 mg

ITA: INTERCEPTOR PLUS film-coated tablets 2.3 mg/46 mg for dogs
ITA: INTERCEPTOR PLUS film-coated tablets 5.75 mg/115 mg for dogs
ITA: INTERCEPTOR PLUS film-coated tablets 11.5 mg/230 mg for dogs
ITA: INTERCEPTOR PLUS film-coated tablets 23 mg/460 mg for dogs

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

Active ingredients: milbemycin oxime and lufenuron
Tablets are available in 4 different sizes:

Weight of dog and colour code of outer pack	Milbemycin Oxime per tablet	Lufenuron per tablet	Excipients q.s. to
Up to 4.5 kg red	2.30 mg	46 mg	156 mg
5 to 11 kg green	5.75 mg	115 mg	390 mg

12 to 22 kg yellow	11.50 mg	230 mg	780 mg
23 to 45 kg white	23.00 mg	460 mg	1560 mg

4. INDICATION(S)

PROGRAM Plus are indicated for the prevention of fleas (*Ct. felis, Ct. canis*, preadult stages), and for the concurrent prevention of heartworm (elimination of L3/L4 larval stages of *Dirofilaria immitis)* and/or treatment of adult stages of gastrointestinal nematodes such as hookworms (*Ancylostoma caninum)*, roundworms (*Toxocara canis)* and whipworms (*Trichuris vulpis*).

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, to the adjuvants or to any of the excipients.

6. ADVERSE REACTIONS

Pale mucous membranes, increased intestinal peristalsis, lethargy, diarrhoea have been observed very rarely after treatment. The treatment of dogs with a high number of circulating microfilariae can sometimes lead to the appearance of moderate and transitory hypersensitivity reactions, such as pale mucous membranes, vomiting, laboured breathing, or excessive salivation. These reactions are associated with the release of proteins from dead or dying microfilariae and are not a direct toxic effect of the product.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog.

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

PROGRAM Plus tablets, available in four sizes, are given according to the weight of the dog, consistent with the administration of a minimum dose of 0.5 mg milbemycin oxime and 10 mg lufenuron per kg body weight.

Colour of container	Body weight (kg)	Posology	mg of milbemycin oxime per tablet	mg of lufenuron per tablet
red	up to 4.5 kg	1 tablet/month	2.3	46

green	from 5 to 11 kg	1 tablet/month	5.75	115
yellow	from 12 to 22 kg	1 tablet/month	11.5	230
white	from 23 to 45 kg	1 tablet/month	23	460

For dogs greater than 45 kg, a combination of tablets is given, consistent with the recommended minimum dose.

PROGRAM Plus should be administered in the following situations:

Puppies:
To prevent flea infestations with concurrent heartworm prevention and/or gastrointestinal nematode infection medication should start from 2 weeks of age, or from a minimum weight of 1 kg.

Dogs in a non-heartworm region:
PROGRAM Plus can be used as part of the seasonal prevention of fleas replacing lufenuron mono (PROGRAM tablets) in cases with diagnosed concurrent gastrointestinal nematode infection. After elimination of the nematode infection confirmed by faecal examination, prevention of fleas should continue with PROGRAM tablets if indicated.

In puppies, treatment with PROGRAM Plus is recommended up to one month after weaning. Thereafter, prevention of fleas can be continued with lufenuron mono (PROGRAM).

Dogs travelling to a heartworm region:
To prevent flea infestations with concurrent heartworm prevention, dogs travelling to a heartworm risk region should begin medication within one month after arrival. Treatment should continue monthly, with the last administration given after the dog has left the region.

Dogs in a heartworm region:
To prevent flea infestations and to prevent heartworm, medication should begin within one month after the appearance of mosquitoes, or one month before the appearance of fleas, and continue throughout the risk period with the last dose given within one month after the mosquito and flea season finishes.

If dogs have a high level of flea infestation at the start of treatment, it may be necessary to apply a flea adulticide during the first one to two months. It is important to treat all dogs and cats in the household for fleas. Cats in the same household should be treated with PROGRAM oral or injectable suspension.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure adequate drug absorption, PROGRAM Plus must be administered with food (for example mixed with the daily feed) or placed directly in the mouth after feeding.

Treatment with PROGRAM Plus may begin at any time of the year. In geographic areas where the presence of fleas and mosquitoes (heartworm vector) is seasonal,

depending on ambient temperature, treatment should be started one month prior to the appearance of the insects and then repeated monthly throughout the risk period. In environments with year-round flea infestations and concurrent heartworm risk, treatment may be continued throughout the year without interruption.

Ideally, tablets are administered on the same day each month. If an interval is greater than 6 weeks, treatment should be resumed immediately and be continued at monthly intervals and, in case of heartworm prevention, a veterinarian should be consulted.

PROGRAM Plus immediately block the reproductive cycle of fleas by inhibiting the development of eggs and larvae. Pre-existing generations (e.g. pupae) present in the environment can, however, continue to develop and emerge for several weeks after the start of treatment.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C
Keep the blister strips in the outer carton.
Do not use after the expiry date printed on the carton or blister.

12. SPECIAL WARNING(S)

In heartworm risk regions, or if it is known that a dog has been travelling to and from heartworm risk regions, before commencing PROGRAM Plus treatment as with any other heartworm preventive, a veterinary consultation is advised to exclude the presence of any concurrent infestation of *Dirofilaria immitis*. In the case of a positive diagnosis, adulticidal therapy is indicated before administering PROGRAM Plus.
During treatment with PROGRAM Plus, no other antiparasitic macrocyclic lactones should be administered.
For animal treatment only.
To be sold on presentation of a veterinary prescription only.
In the case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally

15. OTHER INFORMATION

Can be given during pregnancy and lactation.
Carton containers, each containing 6 or 8 pentagonal tablets.
Not all pack sizes may be marketed.

15 August 2016