LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto Plus 500 mg / 25 mg spot-on solution for large cats (>6.25 – 12.5 kg)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

500 mg fluralaner / 25 mg moxidectin

Excipient:
Butylhydroxytoluene 1.07 mg/ml

3. PACKAGE SIZE

1.79 ml
2 x 1.79 ml

4. TARGET SPECIES

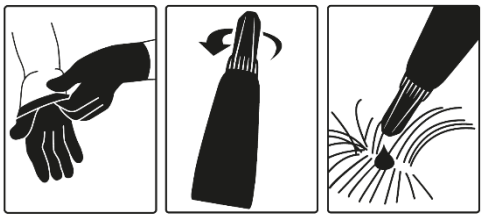
Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

Cap does not come off.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the sachet in the outer carton

Keep the veterinary medicinal product in the sachet until use in order to prevent children from getting access to the product.

The pipettes should be kept in the sachets to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5029

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the skin, mouth and/or eyes. Do not resume contact with the application site until it is no longer noticeable.
Wear gloves when handling and administering this veterinary medicinal product.
Read package leaflet for full user safety information.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto Plus 500 mg / 25 mg spot-on solution for large cats (>6.25 – 12.5 kg)

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

500 mg fluralaner / 25 mg moxidectin

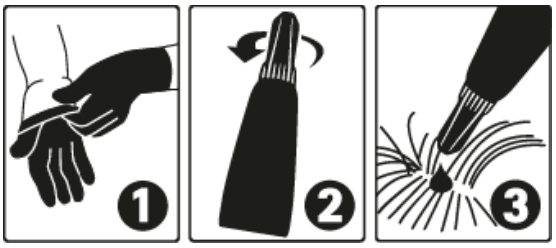
Excipient:
Butylhydroxytoluene 1.07 mg/ml

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
For spot-on use



1. Put on gloves 2. Rotate cap (cap cannot be removed). 3. Apply to skin.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Keep the sachet in the outer carton.
Keep the pipette in the sachet until use.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

1.79 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the skin, mouth and/or eyes. Do not resume contact with the application site until it is no longer noticeable.
Wear gloves when handling and administering this veterinary medicinal product.
Read package leaflet for full user safety information.

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

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

15. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5029

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto Plus

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 mg fluralaner / 25 mg moxidectin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1.79 ml

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bravecto Plus 112.5 mg / 5.6 mg spot-on solution for small cats (1.2 – 2.8 kg)
Bravecto Plus 250 mg / 12.5 mg spot-on solution for medium-sized cats (>2.8 – 6.25 kg)
Bravecto Plus 500 mg / 25 mg spot-on solution for large cats (>6.25 – 12.5 kg)

2. Composition

Active substances:

Each ml of solution contains 280 mg fluralaner and 14 mg moxidectin.
Each pipette delivers:

BRAVECTO PLUS spot-on solution	Pipette content (ml)	Fluralaner (mg)	Moxidectin (mg)
for small cats 1.2 – 2.8 kg	0.4	112.5	5.6
for medium-sized cats >2.8 – 6.25 kg	0.89	250	12.5
for large cats >6.25 – 12.5 kg	1.79	500	25

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Acetone	
Butylhydroxytoluene	1.07 mg/ml
Diethyltoluamide	
Dimethylacetamide	
Glycofurol	

Spot-on solution.
Clear colourless to yellow solution.

3. Target species

Cats

4. Indications for use

For cats with, or at risk from, mixed parasitic infestations by ticks or fleas and ear mites, gastrointestinal nematodes, heartworm or lungworm. The veterinary medicinal product is only indicated when use against ticks or fleas and one or more of the other target parasites is indicated at the same time.

For the treatment of tick and flea infestations in cats providing immediate and persistent flea (*Ctenocephalides felis*) and tick (*Ixodes ricinus)* killing activity for 12 weeks. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For the treatment of infestations with ear mites (*Otodectes cynotis*).

For the treatment of infections with intestinal roundworm (4th stage larvae, immature adults and adults of *Toxocara cati*) and hookworm (4th stage larvae, immature adults and adults of *Ancylostoma tubaeforme*).

When administered repeatedly at a 12-week interval, the veterinary medicinal product continuously prevents heartworm disease caused by *Dirofilaria immitis* (see details in section 9).

Prevention of aelurostrongylosis (by preventing the establishment of adult *Aelurostrongylus abstrusus* responsible for clinical disease).

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Ticks and fleas need to start feeding on the host to become exposed to fluralaner; therefore, the risk of the transmission of parasite borne diseases cannot be excluded.

Cats in areas endemic for heartworm (or those which have travelled to endemic areas) may be infected with adult heartworms. No therapeutic effect against adult *Dirofilaria immitis* has been established. It is therefore recommended, in accordance with good veterinary practice, that animals of 6 months of age or older and living in areas where a vector exists, should be tested for existing adult heartworm infections before application of the veterinary medicinal product for the prevention of heartworm disease. For the prevention of heartworm disease in cats that are only temporarily in endemic areas, the veterinary medicinal product should be applied before the first expected exposure to mosquitoes and should be continued at 12-week intervals until return to a non-endemic area. The period between treatment and return from the endemic areas should not exceed 60 days.

For the treatment of infections with ear mites (*Otodectes cynotis*) or the gastrointestinal nematodes *T*. *cati* and *A*. *tubaeforme*, the need for, and the frequency of, re-treatment as well as the choice of the treatment (monosubstance or combination product) should be evaluated by the prescribing veterinarian.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.
The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class under specific circumstances.
Parasite control is recommended throughout the period of potential infestation risk.

The possibility that other animals in the same household can be a source of re-infection with fleas, ear mites or gastrointestinal nematodes should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

No therapeutic effect against adult *A. abstrusus* has been established. For the treatment of pre-existing infections with adult *A. abstrusus*, administration of a product authorised for treatment of adult *A. abstrusus* is required.

Special precautions for safe use in the target species:
Care should be taken to avoid contact with the eyes of the animal.
Do not use directly on skin lesions.

In the absence of available data, treatment of kittens less than 9 weeks of age and cats less than 1.2 kg bodyweight is not recommended.
Treatment of male breeding animals is not recommended.

This veterinary medicinal product is for topical use and should not be administered orally.
Oral uptake of the veterinary medicinal product at the maximum recommended dose of 93 mg fluralaner + 4.65 mg moxidectin/kg body weight induced some self-limiting salivation or single incidences of vomiting immediately after administration.
It is important to apply the dose as indicated to prevent the animal from licking and ingesting the veterinary medicinal product (see sections 7 and 9).
Do not allow recently treated animals to groom each other.
Do not allow treated animals to come into contact with untreated animals until the application site is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Contact with the veterinary medicinal product should be avoided and disposable protective gloves obtained with this veterinary medicinal product at the point of sale must be worn when handling the veterinary medicinal product for the following reasons:
Hypersensitivity reactions have been reported in a small number of people, which can potentially be serious.
Persons with a hypersensitivity to fluralaner or to any of the excipients should avoid any exposure to the veterinary medicinal product.

The veterinary medicinal product binds to skin and may also bind to surfaces after spillage of the product. Skin rashes, tingling or numbness have been reported in a small number of individuals after skin contact.
If skin contact does occur, wash the affected area immediately with soap and water. In some cases, soap and water are not sufficient to remove the veterinary medicinal product spilled on the fingers.
Contact with the veterinary medicinal product may also occur when handling the treated animal.
Make sure that your animal's application site is no longer noticeable before resuming contact with the site of application. This includes cuddling the animal and sharing a bed with the animal. It takes up to 48 hours for the application site to become dry but it will be noticeable for longer.
If skin reactions occur, consult a physician and show them the veterinary medicinal product packaging.
People with a sensitive skin or known allergy in general e.g., to other veterinary medicinal products of this type should handle the veterinary medicinal product as well as treated animals with caution.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.
This veterinary medicinal product is harmful after ingestion. Keep the veterinary medicinal product in the original packaging until use, in order to prevent children from getting direct access to the veterinary medicinal product. A used pipette should immediately be disposed of. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
The veterinary medicinal product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition. In case of spillage onto, for example table or floor surfaces, remove excess product using paper tissue and clean the area with detergent.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in pregnant or lactating animals and therefore use in such animals is not recommended.

Interaction with other medicinal products and other forms of interaction:
Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with the veterinary medicinal product, other products that can inhibit p-glycoprotein (e.g., cyclosporine, ketoconazole, spinosad, verapamil) should only be used concomitantly according to the benefit-risk assessment of the responsible veterinarian.

Overdose:
No adverse reactions were observed following topical administration to kittens aged 9-13 weeks and weighing 0.9-1.9 kg treated with overdoses of up to 5 times the maximum recommended dose (93 mg fluralaner + 4.65 mg moxidectin, 279 mg fluralaner + 13.95 mg moxidectin and 465 mg fluralaner + 23.25 mg moxidectin/kg body weight) on three occasions at shorter intervals than recommended (8-week intervals).

Special precautions for the protection of the environment:
Not applicable.

7. Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):	Skin reactions at the application site (application site alopecia, flaking skin, application site reddening and application site pruritus)[#].
Uncommon (1 to 10 animals / 1,000 animals treated):	Dyspnoea (after licking the application site), Tachypnoea; Hypersalivation, Emesis, Haematemesis, Diarrhoea; Lethargy, Pyrexia; Mydriasis.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anorexia; Neurological disorders (e.g. tremor, ataxia).

[#]mild and transient

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

For spot-on use.

This veterinary medicinal product is available in three pipette sizes. The following table defines the size of pipette to be used according to the body weight of the cat (corresponding to a dose of 40-94 mg fluralaner/kg body weight and 2-4.7 mg moxidectin/kg body weight):

Weight of cat (kg)	**Pipette size to be used**
1.2 – 2.8	Bravecto Plus 112.5 mg + 5.6 mg spot-on solution for small cats
>2.8 – 6.25	Bravecto Plus 250 mg + 12.5 mg spot-on solution for medium-sized cats
>6.25 – 12.5	Bravecto Plus 500 mg + 25 mg spot-on solution for large cats

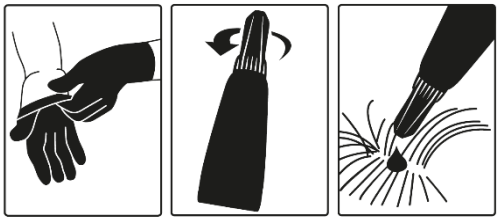
Within each weight band, the content of one whole pipette should be used.
For cats more than 12.5 kg, use a combination of two pipettes that most closely matches the body weight.
Underdosing could result in ineffective use and may favour resistance development.

9. Advice on correct administration

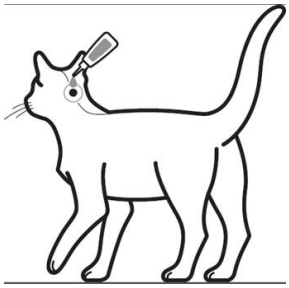
Spot-on use.

Method of administration

Step 1: Immediately before use, open the sachet and remove the pipette. Put on gloves. The pipette should be held by the base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The twist-and-use cap should be rotated clockwise or counter-clockwise one full turn. The cap will stay on the pipette; it is not possible to remove it. The pipette is open and ready for application when the breaking of the seal is felt.



Step 2: The cat should be standing or lying with its back horizontal for easy application. Place the pipette tip on the base of the skull of the cat.



Step 3: Squeeze the pipette gently and apply the entire contents directly to the cat's skin. The veterinary medicinal product should be applied on cats up to 6.25 kg body weight in one spot at the base of the skull and in two spots at the base of the skull on cats greater than 6.25 kg bodyweight.

Treatment

For the concurrent treatment of infections with ear mites (*Otodectes cynotis*), a single dose of the veterinary medicinal product should be applied. Seek further veterinary examination (i.e., otoscopy) 28 days after treatment to determine whether there is re-infestation requiring additional treatment. The choice of the additional treatment (monosubstance or combination product) should be determined by the prescribing veterinarian.

For the concurrent treatment of infections with the gastrointestinal nematodes *T. cati* and *A. tubaeforme*, a single dose of the veterinary medicinal product should be applied. The need for and frequency of re-treatment should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

Where necessary, cats can be re-treated at 12-week intervals.

Cats in areas endemic for heartworm, or cats which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to application of the veterinary medicinal product for the concurrent prevention of infection with adult *D. immitis*, the advice provided in section 6 should be considered.

At the time of treatment, the product is effective against *D. immitis* larvae (L3 and L4), which have infected the cat in the previous 30 days.

The veterinary medicinal product is effective against incoming *D. immitis* larvae (L3) for 60 days after treatment.

Therefore, for continuous prevention of heartworm disease cats need to be retreated at 12-week intervals.
To prevent the establishment of adult lungworms responsible for clinical aelurostrongylosis, cats need to be retreated at 12-week intervals.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
The pipettes should be kept in the sachet to prevent solvent loss or moisture uptake.
The sachets should only be opened immediateley prior to use.

Do not use this veterinary medicinal product after the expiry date stated on the packaging after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as fluralaner and moxidectin may be dangerous for fish and other aquatic organisms.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/5029

Each cardboard box contains 1 or 2 pipettes and a pair of gloves per pipette.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

August 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

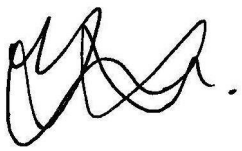
Manufacturer responsible for batch release:
Intervet Productions
Rue de Lyons
27460 Igoville
France

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel: + 44 (0)1908 685685

17. Other information

The product contributes towards the control of environmental flea populations in areas to which treated cats have access.
The onset of effect (killing effect) for ticks (*I. ricinus*) and fleas (*C. felis*) is within 48 hours after treatment.

POM-V To be supplied only on veterinary prescription



Approved: 05 September 2023