FOR EXTERNAL ANIMAL USE ONLY

BRAVECTO® PLUS
Reg. No. G4408 (Act 36/1947)
For Small Cats
For Medium Cats
For Large Cats

INDICATIONS

For cats suffering from, or at risk of, mixed ecto- and endoparasitic infestations.

- For the treatment of tick and flea infestations in cats. **Bravecto® Plus** is a systemic insecticide and acaricide that provides immediate and persistent flea (*Ctenocephalides felis*) and tick (*Ixodes ricinus, Ixodes scapularis, Rhipicephalus sanguineus* and *Haemaphysalis* spp.) killing activity for 3 months.
- For the treatment of ear mites (*Otodectes cynotis*) in cats.
- For the prevention of heartworm disease caused by *Dirofilaria immitis* for 3 months.
- For the treatment of infestations of intestinal roundworm (*Toxocara cati*; fourth stage larvae, immature adults and adults) and hookworm (*Ancylostoma tubaeforme*; fourth stage larvae, immature adults and adults).

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.
Bravecto® Plus can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

CAUTION

STORAGE

- Store at or below 30 °C.
- The pipettes should be kept in the outer packaging to prevent solvent loss or moisture uptake.
- The sachets should only be opened immediately prior to use.

COMPOSITION

Each 1 mℓ of **Bravecto® Plus** contains **280 mg fluralaner** and **14 mg moxidectin.**
Each pipette of **Bravecto® Plus** delivers:

Bravecto® Plus	**Pipette content (mℓ)**	**Fluralaner (mg)**	**Moxidectin (mg)**
Small cats 1,2 to 2,8 kg	0,4	112,5	5,6
Medium cats > 2,8 to 6,25 kg	0,89	250	12,5
Large cats > 6,25 to 12,5 kg	1,79	500	25

Excipient(s):
Butylhydroxytoluene 1,07 mg/mℓ

WARNINGS

- Parasites 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.
- The use of **Bravecto® Plus** should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species, in order to limit the possibility of a future selection for resistance. Parasite control is recommended throughout the period of potential infestation risk.
- The efficacy of **Bravecto® Plus** in controlling tapeworm infestations in cats has not yet been determined.
- Keep **Bravecto® Plus** in the original packaging until use.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Dispose of empty containers and unused product according to local waste disposal regulations and do not reuse for any other purpose.
- The safety of **Bravecto® Plus** has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.
- Although this remedy has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- 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 *D. immitis* has been established. It is

therefore recommended, in accordance with good veterinary practice, that all animals 6 months of age or more, living in areas where a vector exists should be tested for existing adult heartworm infections before beginning preventive use with **Bravecto® Plus**.

- To ensure continuous prevention of heartworm disease, a repetition of treatment is necessary at 3-month intervals. At the time of treatment, **Bravecto® Plus** is effective against *D. immitis* larvae (L3 and L4), which have developed in the previous 30 days and against incoming *D. immitis* larvae (L3 and L4) for the subsequent 60 days.
- Prevention of heartworm disease in cats that are only temporarily in endemic areas should start at the latest within 1 month after the first expected exposure to mosquitoes and should be continued at 12-week intervals until return to a non-endemic area.
- For the treatment of infestations with the gastrointestinal nematodes *T. cati* and *A. tubaeforme*, the need for, and the frequency of retreatment as well as the choice of the treatment (monosubstance or combination product) should be evaluated by the prescribing veterinarian.
- Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class under specific circumstances. The use of **Bravecto® Plus** should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance. Parasite control is recommended throughout the period of potential infestation risk.
- Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of **Bravecto® Plus** in these cases has not been tested.

Special precautions for use in animals

- 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 younger than 9 weeks of age and cats less than 1,2 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.
- Treatment of male breeding animals is not recommended due to an observed decrease in spermatogenesis in male rats during toxicology studies of moxidectin. The impact of **Bravecto® Plus** on mating performance, sperm quality, fertility or offspring data has not been tested in male cats.
- **Bravecto® Plus** should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested.
- **Bravecto® Plus** is for topical use and should not be administered orally.
- It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product.
- 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

- **Bravecto® Plus** is harmful after ingestion.
- Keep **Bravecto® Plus** in the original packaging until use, in order to prevent children from getting direct access to the 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.
- This product, and the wet skin of a recently treated animal, may be slightly irritating to the skin and moderately irritating to the eyes.
- Avoid contact with skin, mouth and/or eye, including hand-to-mouth and/or hand-to-eye contact.
- Do not eat, drink or smoke while handling the product.
- Do not come into contact or allow children to come into contact with the application site until it is dry; it is therefore recommended to treat the animal in the evening. On the day of treatment, treated animals should not be permitted to sleep in the same bed as their owner, especially children.
- Wash hands thoroughly with soap and water immediately after use of the product. If skin contact does occur, wash the affected area immediately with water. In some cases, water is not sufficient to remove the product spilled on the fingers. If a sticky residue persists on the skin after washing with water, then this can be removed using household items containing organic solvents [e.g. rubbing alcohol (ethanol, isopropyl alcohol) or nail polish remover (acetone)] applied gently with a swab.
- In case of contact with the eyes, immediately rinse thoroughly with water.
- The product is highly flammable. Keep away from heat, sparks, open flames or other sources of ignition.

DIRECTIONS FOR USE – USE ONLY AS DIRECTED

- For topical spot-on use.
- **Bravecto® Plus** is available in 3 pipette sizes. The following table defines the size of pipette to be used according to the bodyweight of the cat (corresponding to a dose of 40 to 94 mg fluralaner/kg bodyweight and 2 to 4,7 mg moxidectin/kg bodyweight):

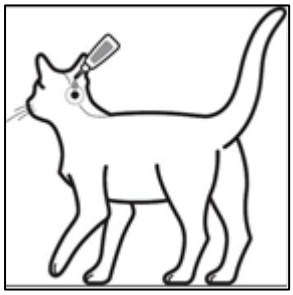
Weight of cat (kg)	**Pipette size to be used**
1,2 to 2,8	**Bravecto® Plus** 112,5 mg & 5,6 mg spot-on solution for small cats
> 2,8 to 6,25	**Bravecto® Plus** 250 mg & 12,5 mg spot-on solution for medium cats
> 6,25 to 12,5	**Bravecto® Plus** 500 mg & 25 mg spot-on solution for large cats

Within each weight band, the content of 1 whole pipette should be used.
For cats more than 12,5 kg, use a combination of 2 pipettes that most closely matches the bodyweight.

Advice on correct administration
Method of administration
Step 1: Immediately before use, open the sachet and remove the pipette. 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 1 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 horizontally during application. Part the fur at the administration site. Place the pipette tip vertically against the skin 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. **Bravecto® Plus** should be applied in 1 spot (cats up to 6,25 kg bodyweight) or 2 spots (cats weighing more than 6,25 kg bodyweight). If 2 spots are needed, the first spot should be applied at the base of the skull and the second one between the shoulder blades.
It is important to deliver the solution onto an area that cannot be easily licked by the cat. As cats are fastidious groomers, they may inadvertently ingest product if easily reached. Ingestion may cause adverse reactions and will remove product from the coat. If multiple cats are treated and may mutually groom, it is recommended that cats are separated while product dries.



Treatment schedule
For optimal control of tick and flea infestation and for prevention of heartworm disease, **Bravecto® Plus** should be administered at intervals of 3 months.

In fast growing kittens it is recommended to re-administer **Bravecto® Plus** after 8 weeks to ensure continuous heartworm prevention.

Cats in areas endemic for heartworm or those which have travelled to endemic areas may be infected with adult heartworms. Therefore prior to treatment with **Bravecto® Plus**, the advice provided under "PRECAUTIONS" should be considered.

For the treatment of infestations with gastrointestinal nematodes, the treatment schedule should be based on veterinary diagnosis and on the local epidemiological situation.

CONTRA-INDICATIONS
Do not use in case of hypersensitivity to any of the active substances or to any of the excipients.

ADVERSE REACTIONS
Mild and transient skin reactions at the application site [alopecia (hair loss), flaking skin and pruritus (itchy skin)] were observed in clinical trials (2,9 % of treated cats).

The following other reactions were uncommonly observed in clinical trials shortly after administration: dyspnoea (difficulty breathing) after licking the application site, hematemesis (bloody vomit), diarrhoea, lethargy, hypersalivation (excess drooling), pyrexia (fever), tachypnoea (rapid breathing), mydriasis (dilated pupils) (0,1 % of treated cats).

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

OVERDOSE
No adverse reactions were observed following topical administration to kittens aged 9 to 13 weeks and weighing 0,9 to 1,9 kg treated with overdoses of up to 5 times the maximum recommended dose (93 mg fluralaner and 4,65 mg moxidectin, 279 mg fluralaner and 13,95 mg moxidectin and 465 mg fluralaner and 23,25 mg moxidectin/kg bodyweight) on 3 occasions at shorter intervals than recommended (8-week intervals).
Oral uptake of the product at the maximum recommended dose of 93 mg fluralaner and 4,65 mg moxidectin/kg bodyweight was well tolerated in cats, apart from some self-limiting salivation (drooling) or single incidences of vomiting immediately after administration.

NOTES FOR THE VETERINARIAN
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 **Bravecto® Plus**, 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.
The safety of concurrent use of Bravecto® Plus and praziquantel (at a dose of 16,7 mg/kg bodyweight) has been confirmed.

Pharmacodynamic properties
Fluralaner is an acaricide and insecticide. It is efficacious against ticks (*I. ricinus*, *I. scapularis*, *R. sanguineus* and *H.* spp.), fleas (*C. felis*) and ear mites (*O. cynotis*) in cats. The onset of effect is within 48 hours for ticks (*I. ricinus*) and within 12 hours for fleas (*C. felis*) after treatment. Fluralaner has a high potency against ticks and fleas by exposure via feeding, i.e. it is systemically active on target parasites.

Fluralaner is a potent inhibitor of parts of the arthropod nervous system by acting antagonistically on ligand-gated chloride channels (GABA-receptor and glutamate-receptor). In molecular on-target studies on insect GABA receptors of flea and fly, fluralaner is not affected by dieldrin resistance. In *in vitro* bio-assays, fluralaner is not affected by proven field resistances against amidines (tick), organophosphates (tick, mite), cyclodienes (tick, flea, fly), macrocyclic lactones (sea lice), phenylpyrazoles (tick, flea), benzophenyl ureas (tick), pyrethroids (tick, mite) and carbamates (mite).

Bravecto® Plus contributes towards the control of the environmental flea populations in areas to which treated cats have access. Newly emerged fleas on a cat are killed before viable eggs are produced. An *in vitro* study also demonstrated that very low concentrations of fluralaner stop the production of viable eggs by fleas.
The flea life cycle is broken due to the rapid onset of action and long-lasting efficacy against adult fleas on the animal and the absence of viable egg production.

Moxidectin, a semisynthetic derivative of nemadectin, belongs to the milbemycin group of macrocyclic lactones (avermectins being the other) and has parasiticidal activity against a range of internal and external parasites including various nematode species as well as mites, lice, warble and horn flies. Moxidectin lacks substantial efficacy against fleas and ticks. Moxidectin is only active on larvae (L3 and L4) of *D. immitis* and not on adult worms.

Milbemycins and avermectins have a common mode of action that is based on the binding of ligand-gated chloride channels (glutamate-R and GABA-R). This leads to an increased membrane permeability of nematode and arthropod nerve and/or muscle cells for chloride ions and results in hyperpolarisation,

paralysis and death of the parasites. Binding of glutamate-gated chloride channels, which are specific to invertebrates and do not exist in mammals, is considered the main mechanism for the anthelmintic and insecticidal activity.

PRESENTATION
Clear, colourless to yellow solution presented in unit dose pipettes made of laminated aluminium/ polypropylene foil, closed with high density polyethylene (HDPE) caps and packed in laminated aluminium foil sachets.
Each carton box contains 1 or 2 pipettes in either small, medium or large doses.
Not all pack sizes may be marketed.

REGISTRATION HOLDER
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SLEGS VIR UITWENDIGE DIEREGEBRUIK

BRAVECTO® PLUS
Reg. Nr. G4408 (Wet 36/1947)
Vir Klein Katte
Vir Medium Katte
Vir Groot Katte

INDIKASIES
Vir katte wat aan gemengde ekto- en endoparasitiese besmettings ly, of die gevaar loop daarvan.

- Vir die behandeling van bosluis- en vlooibesmettings by katte. **Bravecto® Plus** is 'n sistemiese insekdoder en mytdoder wat onmiddellike en aanhoudende vlooi- (*Ctenocephalides felis*) en bosluisdodende (*Ixodes ricinus, Ixodes scapularis, Rhipicephalus sanguineus* en *Haemaphysalis* spp.) aktiwiteit bied vir 3 maande.
- Vir die behandeling van oormyte (*Otodectes cynotis*) in katte.
- Vir die voorkoming van hartwurmsiekte wat deur *Dirofilaria immitis* veroorsaak word, vir 3 maande.
- Vir die behandeling van besmettings met intestinale rondewurm (*Toxocara cati*; vierde stadium larwes, onvolwassenes en volwassenes) en haakwurm (*Ancylostoma tubaeforme*; vierde stadium larwes, onvolwassenes en volwassenes).

Vlooie en bosluise moet aan die gasheer vasheg en begin voed om aan die aktiewe bestanddeel blootgestel te word.
Bravecto® Plus kan gebruik word as deel van 'n behandelingstrategie vir vlooi allergiese dermatitis (VAD).

VERSIGTIG

BERGING

- Berg teen of benede 30 °C.
- Die pipette moet in die buitenste verpakking gehou word om verlies van oplosmiddel of vogopname te voorkom.
- Die sakkies moet slegs direk voor gebruik oopgemaak word.

SAMESTELLING
Elke 1 mℓ **Bravecto® Plus** bevat **280 mg fluralaner** en **14 mg moksidektien.**
Elke pipet **Bravecto® Plus** verskaf:

Bravecto® Plus	**Pipetinhoud (mℓ)**	**Fluralaner (mg)**	**Moksidektien (mg)**
Klein katte 1,2 tot 2,8 kg	0,4	112,5	5,6
Medium katte > 2,8 tot 6,25 kg	0,89	250	12,5
Groot katte > 6,25 tot 12,5 kg	1,79	500	25

Hulpmiddel(s):
Butielhidroksitolueen 1,07 mg/mℓ

WAARSKUWINGS

- Parasiete moet op die gasheer begin voed om blootgestel te word aan fluralaner; daarom kan die risiko van oordrag van parasietoordraagbare siektes nie uitgesluit word nie.
- Die gebruik van **Bravecto® Plus** moet gebaseer word op die beoordeling van elke individuele geval en op plaaslike epidemiologiese inligting oor die huidige vatbaarheid van die teikenspesie ten einde die moontlikheid van 'n toekomstige seleksie vir weerstand te beperk. Parasietbeheer word aanbeveel gedurende die hele periode van moontlike infeksierisiko.
- Die effektiwiteit van **Bravecto® Plus** in die beheer van lintwurmbesmettings in katte is nog nie bepaal nie.
- Hou **Bravecto® Plus** in die oorspronklike verpakking tot net voor gebruik.
- HOU BUITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Doen weg met leë houers en ongebruikte produk volgens plaaslike afvalbestuursregulasies en moenie vir enige ander doeleinde hergebruik nie.
- Die veiligheid van **Bravecto® Plus** is nie vasgestel tydens dragtigheid en laktasie nie. Gebruik slegs volgens die voordeel-risikobeoordeling deur die verantwoordelike veearts.
- Alhoewel hierdie produk breedvoerig onder ’n wye verskeidenheid toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg ’n veearts en verwittig die registrasiehouer.

VOORSORGMAATREëLS

- Katte in areas waar hartwurm endemies is (of dié wat na endemiese areas gereis het) mag met volwasse hartwurms besmet wees. Geen terapeutiese effek teen volwasse *D. immitis* is vasgestel nie. Daarom word dit aanbeveel dat, in ooreenstemming met goeie veterinêre praktyk, alle diere van 6 maande of ouer, wat in areas woon waar 'n vektor bestaan, getoets moet word vir bestaande volwasse hartwurminfeksies voordat voorkomende gebruik met **Bravecto® Plus** begin word.
- Om deurlopende voorkoming van hartwurmsiekte te voorkom, is herhaling van die behandeling nodig met intervalle van 3 maande. Ten tye van behandeling is **Bravecto® Plus** effektief teen *D. immitis* larvae (L3 en L4), wat in die voorafgaande 30 dae ontwikkel het, en teen *D. immitis* larvae (L3 en L4) vir die daaropvolgende 60 dae.
- Die voorkoming van hartwurmsiekte in katte wat slegs tydelik in endemiese gebiede is, moet op die laatste binne 1 maand na die eerste verwagte blootstelling aan muskiete begin, en moet met intervalle van 12 weke voortgesit word totdat hulle na 'n nie-endemiese area terugkeer.
- Vir die behandeling van besmettings met gastrointestinale nematodes, *T. cati* en *A. tubaeforme* moet die behoefte aan, en die herhaling van behandeling, sowel as die keuse van die behandeling (enkelbestanddeel of kombinasieproduk) deur die voorskrywende veearts geëvalueer word.
- Parasietweerstand teen enige spesifieke klas wurmmiddel kan ontwikkel ná gereelde, herhaalde gebruik van 'n wurmmiddel in daardie klas, onder spesifieke omstandighede. Die gebruik van **Bravecto® Plus** moet gebaseer word op die beoordeling van elke individuele geval en op plaaslike epidemiologiese inligting oor die huidige vatbaarheid van die teikenspesie ten einde die moontlikheid van 'n toekomstige seleksie vir weerstand te beperk. Parasietbeheer word aanbeveel gedurende die hele periode van moontlike infeksierisiko.
- Verhoed dat die dier gereeld swem of gesjampoe word aangesien die doeltreffendheid van **Bravecto® Plus** in hierdie gevalle nie getoets is nie.

Spesiale voorsorgmaatreëls vir gebruik in diere

- Sorg moet gedra word om kontak met die dier se oë te vermy.
- Moenie direk op velletsels gebruik nie.
- In die afwesigheid van beskikbare data moet die behandeling van katjies jonger as 9 weke en katte met 'n gewig van minder as 1,2 kg gebaseer wees op 'n voordeel-risikobeoordeling deur die verantwoordelike veearts.
- Behandeling van manlike teeldiere word nie aanbeveel nie as gevolg van 'n waargenome afname in spermatogenese by manlike rotte tydens toksikologiese studies. Die impak van **Bravecto® Plus** op paringsprestasie, spermkwaliteit, vrugbaarheid of nageslag data is nog nie by manlike katte getoets nie.
- **Bravecto® Plus** moenie teen intervalle van korter as 8 weke toegedien word nie, aangesien die veiligheid met korter intervalle nie getoets is nie.
- **Bravecto® Plus** is vir topikale gebruik alleenlik, vermy orale inname.
- Dit is belangrik om die dosis toe te dien soos aangedui om te voorkom dat die dier die produk lek en inneem.
- Moenie toelaat dat diere wat onlangs behandel is, mekaar versorg nie.
- Moenie toelaat dat behandelde diere met onbehandelde diere in aanraking kom voordat die toedieningsplek droog is nie.

Spesiale voorsorgmaatreëls wat deur die persoon wat die dieremedisyne aan diere toedien getref moet word

- **Bravecto® Plus** is skadelik na inname.
- Hou **Bravecto® Plus** in die oorspronklike verpakking tot voor gebruik, om sodoende kinders te verhoed om direkte toegang tot die produk te verkry.
- 'n Gebruikte pipet moet onmiddellik weggegooi word.
- In die geval van toevallige inname, verkry mediese hulp en toon die voubiljet of etiket aan die geneesheer.
- Hierdie produk, en die nat vel van 'n pas behandelde dier, kan effens irriterend vir die vel wees en matig irriterend vir die oë.
- Vermy kontak met die vel, mond en/of oog, insluitend hand-tot-mond en/of hand-tot-oog-kontak.
- Moenie eet, drink of rook terwyl die produk hanteer word nie.
- Moenie in aanraking kom, of kinders toelaat om met die toedieningsplek in aanraking te kom voordat dit droog is nie; daarom word dit aanbeveel om die dier in die aand te behandel. Op die dag van behandeling moet behandelde diere nie toegelaat word om in dieselfde bed as hul eienaar, veral kinders, te slaap nie.
- Was hande deeglik met seep en water onmiddellik nadat die produk gebruik is. Was kontak met die vel onmiddellik met water. In sommige gevalle is water nie voldoende om die produk wat op die vingers gemors is, te verwyder nie. As 'n klewerige oorskot op die vel voortduur nadat dit met water gewas is,

kan dit verwyder word met huishoudelike items wat organiese oplosmiddels bevat [bv. aanvryfalkohol (etanol, isopropielalkohol) of naellakverwyderaar (asetoon)] wat versigtig met 'n depper toegedien moet word.
- Spoel onmiddellik en deeglik met water in geval van kontak met die oë.
- Die produk is hoogs vlambaar. Hou weg van hitte, vonke, oop vlamme en ander vorms van ontbranding.

GEBRUIKSAANWYSINGS – GEBRUIK SLEGS SOOS AANGEDUI
- Vir topikale kolbehandeling.
- **Bravecto® Plus** is in 3 pipetgroottes beskikbaar. Die volgende tabel definieer die groottes van die pipette wat gebruik moet word volgens die liggaamsgewig van die kat (ooreenstemmend met 'n dosis van 40 tot 94 mg fluralaner/kg liggaamsgewig en 2 tot 4,7 mg moksiedektien/kg liggaamsgewig):

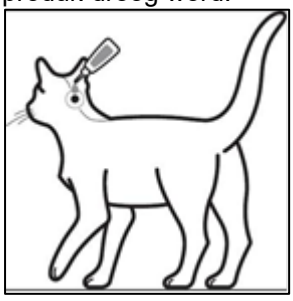
Gewig van kat (kg)	Pipetgrootte wat gebruik moet word
1,2 tot 2,8	**Bravecto® Plus** 112,5 mg & 5,6 mg kolbehandeling vir klein katte
> 2,8 tot 6,25	**Bravecto® Plus** 250 mg & 12,5 mg kolbehandeling vir medium katte
> 6,25 tot 12,5	**Bravecto® Plus** 500 mg & 25 mg kolbehandeling vir groot katte

Die inhoud van 1 pipet moet binne elke gewigsgroep gebruik word.
Katte wat meer as 12,5 kg weeg, moet 'n kombinasie van 2 pipette, wat die naaste aan die liggaamsgewig is, gebruik word.

Advies vir korrekte toediening
Metode van toediening
Stap 1: Onmiddellik voor gebruik, maak die sakkie oop en verwyder die pipet. Die pipet moet vasgehou word op die boonste gedeelte van die stertbasis (geriffelde punt) of deur die boonste stewige gedeelte onder die doppie in 'n regop posisie (doppie boontoe) te hou, voordat dit oopgemaak word. Die doppie moet kloksgewys of antikloksgewys gedraai word vir een volle draai. **Die doppie sal op die pipet bly; dit is nie moontlik om dit te verwyder nie.** Die pipet is oop en gereed vir toediening wanneer die verbreking van die seël gevoel word.

Stap 2: Die kat moet staan of met sy rug horisontaal lê tydens toediening. Skei die hare by die toedieningsplek. Plaas die pipetpunt vertikaal teen die vel op die basis van die skedel van die kat.

Step 3: Druk die pipet liggies en dien die hele inhoud direk op die kat se vel toe. **Bravecto® Plus** moet toegedien word op 1 plek (katte met ‘n liggaamsgewig wat tot en met 6,25 kg) of 2 plekke (katte met ‘n liggaamsgewig meer as 6,25 kg). As 2 plekke nodig is, moet die eerste plek op die basis van die skedel en die tweede plek tussen die skouerblaaie wees.
Dit is belangrik om die oplossing toe te dien op 'n area wat nie maklik deur die kat gelek kan word nie. Aangesien katte puntenerige versorgers is, kan hulle per ongeluk die produk in kry as dit te maklik bereik kan word. Inname mag nadelige reaksies veroorsaak en sal die produk van die pels verwyder. Indien meer katte behandel word wat mekaar onderling versorg, word dit aanbeveel dat katte geskei word terwyl die produk droog word.



Behandelingskedule:
Vir optimale beheer van vlooi- en bosluisbesmetting en die voorkoming van hartwurmsiekte, moet **Bravecto® Plus** met tussenposes van 3 maande toegedien word.

In vinnig groeiende katjies word dit aanbeveel dat **Bravecto® Plus** weer na 8 weke toegedien word om voortdurende voorkoming van hartwurms te verseker.

Katte in areas waar hartwurm endemies is of dié wat na endemiese areas gereis het, mag met volwasse hartwurms besmet wees. Daarom moet die advies wat onder “VOORSORGMAATREëLS” gegee word, oorweeg word voor behandeling met **Bravecto® Plus**.

Vir die behandeling van besmettings met gastroïntestinale nematodes, moet die behandelingskedule gebaseer wees op veterinêre diagnose en op die plaaslike epidemiologiese situasie.

KONTRA-INDIKASIES
Moenie gebruik word in die geval van hipersensitiwiteit tot enige van die aktiewe bestanddele of vir een van die hulpstowwe nie.

NEWE-EFFEKTE
Matige en verbygaande velreaksies by die aanwendingsarea [alopesie (haarvelies), vlokkerige vel en pruritus (jeukerige vel)] was opgemerk in kliniese proewe (2,9 % van behandelde katte).

Die volgende ander reaksies is buitengewoon opgemerk in die kliniese proewe kort na behandeling: dispnee (moeilike asemhaling) nadat die aanwendingsarea gelek is, hematemesis (bloederige braaksel), diarree, lusteloosheid, hipersalivering (oormatige kwyling), pireksie (koors), tagipnee (vinnige asemhaling), midriase (gedilateerde pupille) (0,1 % van behandelde katte).

Stel u veearts in kennis indien u ernstige gevolge of ander gevolge opmerk wat nie in hierdie voubiljet genoem word nie.

OORDOSERING
Geen newe-effekte is waargeneem na topikale toediening aan katjies van 9 tot 13 weke, wat 0,9 tot 1,9 kg weeg en wat behandel is met oordosisse van tot en met 5 keer die maksimum aanbevole dosis (93 mg fluralaner en 4,65 mg moksidektien, 279 mg fluralaner en 13,95 mg moksidektien en 465 mg fluralaner en 23,25 mg moksidektien/kg liggaamsgewig) by 3 geleenthede met korter tussenposes as wat aanbeveel is (tussenposes van 8 weke) nie.
Mondelikse opname van die produk teen 'n maksimum aanbevole dosis van 93 mg fluralaner en 4,65 mg moksidektien/kg liggaamsgewig is goed verdra by katte, afgesien van 'n mate van selfbeperkende speeksel (kwyl) of enkele voorkoms van braking onmiddellik na toediening.

NOTAS VIR DIE VEEARTS
Interaksie met ander medisinale produkte en ander vorme van interaksie
Daar is aangetoon dat makrosikliese laktone, waaronder moksidektien, substrate vir p-glikoproteïen is. Daarom, tydens die behandeling met **Bravecto® Plus**, moet ander produkte wat p-glikoproteïen (bv. siklosporien, ketokonasool, spinosad, verapamil) kan rem, slegs gelyktydig gebruik word volgens die voordeel-risikobeoordeling van die verantwoordelike veearts.
Die veiligheid van die gelyktydige gebruik van Bravecto® Plus en praziquantel (teen 'n dosis van 16,7 mg/kg liggaamsgewig) is bevestig.

Farmakodinamiese eienskappe
Fluralaner is ‘n myt- en insekdoder. Dit is effektief teen bosluise (*I. ricinus*, *I. scapularis*, *R. sanguineus* en *H.* spp.), vlooie (*C. felis*) en oormyte (*O. cynotis*) in katte. Die aanvang van effektiwiteit is binne 48 ure vir bosluise (*I. ricinus*) en binne 12 ure vir vlooie (*C. felis*) na behandeling. Fluralaner is hoogs effektief teen bosluise en vlooie deur blootstelling via voeding, d.w.s. dit is sistemies aktief op teikenparasiete.

Fluralaner is ‘n potente inhibeerder van dele van die geleedpotiges se senuweestelsel deur antagonisties op die ligandbeheerde chloriedkanale (GABA-reseptor en glutamaat-reseptor) te werk. In molekulêre teikenstudies, was fluralaner nie geaffekteer deur dieldrienweerstand nie. In *in vitro* bio-toetse, word fluralaner nie beïnvloed deur bewese veldweerstand teen amidiene (bosluise), organofosfate (bosluise, myte), siklodiëne (bosluise, vlooie, vlieë), makrosikliese laktone (seeluise), fenielpirasole (bosluise, vlooie), bensofenielureas (bosluise), piretroïede (bosluise, myte) en karbamate (myte) nie.

Bravecto® Plus dra by tot die beheer van die vlooibevolking in die omgewing waar behandelde katte toegang het. Vlooie op 'n kat wat pas te voorskyn gekom het, word doodgemaak voordat lewensvatbare eiers geproduseer word. 'n *In vitro*-studie het ook getoon dat baie lae konsentrasies van fluralaner die produksie van lewensvatbare eiers deur vlooie stop.

Die vlooi se lewensiklus word verbreek as gevolg van die vinnige aanvang van werking en langdurige effektiwiteit teen volwasse vlooie op die dier en die afwesigheid van lewensvatbare eierproduksie.

Moksidektien, 'n semi-sintetiese derivaat van nemadektien, behoort aan die milbemisien-groep van makrosikliese laktone (waarvan die avermektiene die ander is) en het parasitiedodende werking teen 'n verskeidenheid interne en eksterne parasiete, waaronder verskillende nematodespesies, sowel as myte, luise, beesvlieë en horingvlieë. Moksidektien het nie 'n wesenlike effektiwiteit teen vlooie en bosluise nie. Moksidektien is slegs aktief op larwes (L3 en L4) van *D. immitis* en nie op volwasse wurms nie.

Milbemisien en avermektien het 'n algemene manier van werking wat gebaseer is op die binding van ligandbeheerde chloriedkanale (glutamaat-R en GABA-R). Dit lei tot 'n verhoogde membraandeurlaatbaarheid van nematode- en geleedpotige senuwee- en/of spierselle vir chloriedione en lei tot hiperpolarisasie, verlamming en dood van die parasiete. Binding van glutamaatbeheerde chloriedkanale, wat spesifiek vir ongewerweldes is en nie by soogdiere bestaan nie, word beskou as die belangrikste meganisme vir die wurmmiddel en insekdoder se werking.

AANBIEDING
Deurskynende, kleurlose tot geel oplossing wat in enkeldosis pipette van gelamineerde aluminium/polipropileenfoelie aangebied word en toegemaak word met hoë-digtheidspoliëtileen (HDPE) proppies, verpak in gelamineerde foeliesakkies.
Elke kartonboksie bevat 1 of 2 pipette vir klein óf medium óf groot dosisse.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

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