**EPAR summary for the public**

**Broadline**

fipronil/(S)-methoprene/eprinomectin/praziquantel

This is a summary of the European public assessment report (EPAR) for Broadline. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Broadline.

For practical information about using Broadline, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

**What is Broadline and what is it used for?**

Broadline is a veterinary medicine used to treat cats with, or at risk of, mixed infestations by tapeworms, roundworms and external parasites (fleas, ticks, and a burrowing mite called *Notoedres* *cati* which is a cause of mange). The product is to be used only when all three groups of parasites are targeted at the same time.

For external parasites, Broadline treats flea infestations and prevents new infestations for at least one month; it also prevents environmental flea contamination for over a month. It may also be used as part of a treatment strategy for flea allergy dermatitis (an allergic reaction to flea bites). It treats tick infestations and prevents new infestations for up to three weeks.

For worms, Broadline is used to treat tapeworms and roundworms in the gut as well as a type of worm that infests the bladder and two types of feline lungworm. Broadline can also be used to prevent heartworm disease for one month.

Broadline contains four active substances: fipronil, (S)-methoprene, eprinomectin and praziquantel.

**How is Broadline used?**

Broadline is available as a spot-on solution in applicators of two different strengths for use in cats of various bodyweights and can only be obtained with a prescription.
The content of one full applicator (appropriate to the cat’s weight) is applied directly to the cat’s skin after parting the hair, in a single spot on the middle of the neck. For lungworm a second treatment may be recommended one month after the initial treatment.

**How does Broadline work?**

Two of the active substances in Broadline, fipronil and (S)-methoprene, act as ‘ectoparasiticides’. This means that they kill external parasites that live on the skin or in the fur of animals, such as fleas and ticks. Two of the active substances in Broadline, eprinomectin and praziquantel, act as ‘endoparasiticides’. This means that they kill parasites that live inside the body of animals.

Fipronil kills adult parasites. It blocks channels in their nerve cells that allow charged chloride particles (ions) to pass, interfering with the transmission of nerve signals and leading to overstimulation and death.

(S)-methoprene is an insect growth regulator which stops the flea life cycle by killing eggs and blocking the development of juvenile flea stages and causing their death.

Eprinomectin interferes with channels in the nerve and muscle cells of roundworms that allow charged chloride particles (ions) to pass, leading to their paralysis and death.

Praziquantel acts on the cell membranes of tapeworms leading to the death of the parasite.

**What benefits of Broadline have been shown in studies?**

The effectiveness of Broadline against fleas and ticks was investigated in an EU field study involving cats infested with fleas, ticks, or both. The study showed effectiveness of 86 to 87% against adult fleas for Broadline throughout the 30 day post-treatment period compared with between 76 and 82% for cats treated with another medicine containing just fipronil and (S)-methoprene. For ticks, effectiveness was between 85 and 93% for Broadline-treated cats compared with 92 and 98% for cats treated with the comparator product.

The effectiveness of Broadline against cat mange was examined in a laboratory study with 18 naturally infested cats. The measure of effectiveness was reduction of the number of *Notoedres cati* mites found in skin scrapings compared to cats that received no treatment. The study showed over 98% effectiveness of the medicine against the mite, with a clinical cure in all animals.

The effectiveness of Broadline against intestinal worms was investigated in one EU field study involving cats with tapeworm or roundworm infections or both. Broadline-treated cats were compared to cats treated with a spot-on product containing the worm medicines emodepside and praziquantel. Effectiveness was measured by identifying adult worm segments (tapeworms) or counting worm eggs (roundworms) in faeces at day 14 after treatment. The study showed almost 100% effectiveness against tapeworms and roundworms for both Broadline and the comparator product.

The effectiveness of Broadline against feline lungworm was investigated in a field study in Italy. Twenty cats naturally infested with lungworm were treated with Broadline. The main measure of effectiveness was reduction of numbers of worm larvae in faeces at 28 days after single treatment. Broadline was more than 90% effective in reducing lungworm larvae at 28 days after treatment and all treated cats showing respiratory signs (such as wheezing, persistent coughing and a runny nose) were clinically cured.

The effectiveness of Broadline to prevent heartworm disease was shown in three laboratory studies, using artificially infested cats. Broadline was 100% effective against the L4 larval stage of heartworm.
What are the risks associated with Broadline?

Mild and short-lived skin reactions (itching, hair loss) may occur at the application site. If the cat licks the application site, temporary excessive salivation may occur. If a cat swallows the medicine it may result in vomiting (being sick) and/or short-lived effects on the nervous system, shown by signs such as lack of muscular coordination, disorientation, lack of interest in surroundings and pupil dilation. All these signs resolve spontaneously within 24 hours.

Broadline must not be used in sick or recovering animals. It must not be used in rabbits or in cases of hypersensitivity (allergy) to any of the ingredients.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

People applying the medicine should not smoke, eat or drink while doing so and should wash their hands after handling the product.

Contact with the applicator should be avoided. If accidental exposure to the eyes occurs, the eyes should be rinsed with water and in case of accidental exposure to the skin, the skin should be washed with soap and water. If eye irritation persists, or if side effects are noticed, medical advice should be sought and the package leaflet or label shown to the doctor.

People with known hypersensitivity to any of the ingredients should avoid contact with the product. Handling of treated animals should be limited until the application site is dry and children should not play with treated animals during this period. Consequently, it is recommended that recently treated animals do not sleep with owners, especially children.

Why is Broadline approved?

The Agency’s Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Broadline’s benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Broadline:

The European Commission granted a marketing authorisation valid throughout the EU for Broadline on 04/12/2013.

The full EPAR for Broadline can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Broadline animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in May 2017.