



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/CVMP/431321/2006
EMA/V/C/000108

EPAR summary for the public

ProMeris Duo metaflumizone and amitraz

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is ProMeris Duo?

ProMeris Duo is a clear, yellow-to-amber solution that contains metaflumizone and amitraz as active substances.

It is given to dogs with a pre-filled spot-on pipette, a small plastic container that is already filled with the correct amount of ProMeris Duo needed to treat one dog. ProMeris Duo is available in five different sizes for various weights of dog. The contents of the pipette are squeezed onto the skin after parting the fur at the back of the head.

What is ProMeris Duo used for?

ProMeris Duo is an 'ectoparasiticide'. This means that it will kill parasites that live on or in the skin or in the fur of animals, such as fleas, ticks, lice and *Demodex* mites (mites that cause demodicosis or 'mange').

ProMeris Duo is used in dogs over eight weeks of age to treat and to prevent tick and flea infestations, and to treat demodicosis (caused by *Demodex* mites) and lice infestations. It can also be used as part of a treatment strategy for the control of flea allergy dermatitis, an allergic reaction to flea bites.



How does ProMeris Duo work?

Both active substances in ProMeris Duo, metaflumizone and amitraz, interfere with the neural activity of the parasites and consequently lead to their death.

How has ProMeris Duo been studied?

Data were provided on pharmaceutical quality, the safety of the medicine in dogs and its safety in humans (people who come into contact with the medicine) and in the environment.

The effectiveness of ProMeris Duo against flea, lice and tick infestations and *Demodex* mites has been studied in a number of studies, including one study in dogs infested with fleas or ticks carried out at veterinary practices in Germany and France. Dogs of various breeds, ages and weights were treated with ProMeris Duo or with other medicines authorised in the European Union (EU) for flea and tick infestation. The effectiveness was measured looking at the number of live ticks or number of fleas on the dogs up to two months after application.

Another study was carried out in dogs with demodicosis in veterinary practices in Italy and Albania. Dogs were treated with ProMeris Duo or the combination of imidacloprid and moxidectin (another medicine authorised in the EU for this indication). The effectiveness was measured looking at the clinical signs and the number of *Demodex* mites in skin scrapings taken every four weeks, for several weeks following monthly administration of the treatment.

A further study compared the effectiveness of ProMeris Duo with that of fipronil (another medicine for the treatment of lice). The effectiveness was measured by looking at the number of lice on the dogs after treatment.

What benefit has ProMeris Duo shown during the studies?

The results of the studies showed that ProMeris Duo is effective in the treatment and prevention of flea and tick infestations, and in the treatment of demodicosis and lice infestation in dogs. The medicine killed most fleas within 24 hours, most ticks within 48 hours and most lice within a week of treatment. Demodicosis was usually cured within three to six months of treatment. The effectiveness of ProMeris Duo lasted for at least six weeks against fleas and for four weeks against ticks.

What is the risk associated with ProMeris Duo?

The most common side effects in dogs are sedation (sleepiness), lethargy (a lack of energy), reduced nervous system activity, hyperglycaemia (high blood sugar levels), bradycardia (slow heart rate), and slow, shallow breathing. These usually disappear without treatment within 24 hours. There may also be a change in appearance of the fur (oily appearance and clumping or spiking of hair) at the application site. In rare cases, temporary irritation may occur at the site of application. In very rare cases, temporary local hair loss may occur.

If a dog licks the application area, the dog might salivate considerably for a short period.

ProMeris Duo must not be used in puppies less than eight weeks old since it has not been sufficiently studied in these animals. As for other products in this group, ProMeris Duo should not be used in sick dogs, dogs that have just recovered from an illness or dogs that are suffering from heat stress. This medicine is specifically developed for dogs and should not be used in any other animal species.

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

As a precautionary measure, avoid direct contact with the treated dog and do not allow children to play with the treated dog until the application site is dry. Recently treated animals should not be allowed to sleep in the same bed as their owners, especially children. ProMeris Duo contains components that, on very rare occasions, can irritate the airways in some people. It is recommended that the product is applied in the open air or in a well-ventilated room.

Amitraz is a monoamine oxidase inhibitor (MOAI). People taking MOAI-containing medicines, such as antidepressants, should take particular care when handling ProMeris Duo.

Avoid touching the skin with the pipette's contents. Protective gloves are recommended when handling the medicine. Wash the skin and rinse eyes with water, if accidental exposure occurs. Do not smoke, eat or drink when applying ProMeris Duo.

ProMeris Duo should not enter surface water, as this may be harmful for fish and other aquatic organisms.

Why has ProMeris Duo been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of ProMeris Duo exceed the risks for the treatment and prevention of flea and tick infestations, and the treatment of demodicosis and lice infestation in dogs. The Committee recommended that ProMeris Duo be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about ProMeris Duo:

The European Commission granted a marketing authorisation valid throughout the European Union for ProMeris Duo on 19 December 2006. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 6 January 2012.