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EPAR summary for the public

Profender

emodepside / praziquantel

This is a summary of the European public assessment report (EPAR) for Profender. 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 use on how to use Profender.

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

What is Profender?

Profender is an antiparasitic medicine that contains two active substances, emodepside and praziquantel. Profender is available as a solution for use on cats, and as modified release tablets for dogs.

Profender solution is packed as spot-on pipettes, which are already filled with the correct amount of Profender needed to treat one cat (3 sizes of pipette for different cat weights) and as a multidose bottle for use only in a veterinary surgery, where the vet will measure the exact volume of Profender needed for each cat before application.

Profender tablets are available in three different strengths to cover a range of dog weights (small, medium or large dogs).

What is Profender and what is it used for?

Profender is a medicine used to treat cats and dogs that have, or are at risk of catching, "mixed" (caused by more than one parasite) parasitic infections. Profender works for infections caused by certain types of roundworms, tapeworms, as well as lungworms in cats.

How is Profender used?

Profender solution is packed as spot-on pipettes, which are already filled with the correct amount of Profender needed to treat one cat (3 sizes of pipette for different cat weights) and as a multidose



bottle for use only in a veterinary surgery, where the vet will measure the exact volume of Profender needed for each cat before application.

Profender tablets are available in three different strengths to cover a range of dog weights (small, medium or large dogs). Profender can only be obtained with a prescription.

Cats are treated using the Profender spot-on solution range. The appropriate quantity of Profender (either the contents of one full pipette or the volume measured by the vet) is applied onto the cat's skin, after parting the fur on the back of its neck at the base of its head.

Dogs are treated using Profender modified-release tablets, which are given by mouth when the dog is fasting. The correct number of tablets or half tablets to use is calculated based on the dog's weight.

Profender is given as a single treatment for roundworms and tapeworms. For lungworms two treatments are needed two weeks apart.

How does Profender work?

The two active substances in Profender interact with different parts of the parasites systems. Emodepside interferes with certain specific receptors in the nervous systems of roundworms, which results in their subsequent paralysis and death. Praziquantel damages the skin-like outer layer of tapeworms, leading to their paralysis and death.

What benefits of Profender have been shown in studies?

The effectiveness of each of the products against the specified roundworms and tapeworms was investigated in both laboratory studies and in large field studies (one for the spot-on for cats and another for the tablets for dogs) carried out at several different places across Europe. In each of the field studies, animals of various breeds, age groups and different weights that were naturally infected with roundworms or tapeworms in their guts, were treated either with Profender or another approved worming medicine (selamectin in cats, and milbemycin oxime and praziquantel in dogs). The effectiveness was measured by looking at the number of worm eggs or parts of tapeworms passed out in the animal's faeces after treatment. The results from the laboratory studies and from the field studies, in both cats and dogs, showed that Profender was as effective as the comparator medicine. Over 90% of cats and 99% of dogs had no roundworm or tapeworm infection after treatment with Profender.

For lungworms in cats a laboratory study together with a field study showed Profender to reduce the number of larvae passed in the animal's faeces by more than 99%. The laboratory study showed Profender to reduce the worm count in the lungs by more than 99%.

What are the risks associated with Profender?

In cats, in very rare cases, the cat might salivate or vomit after treatment. Mild and short-lived signs relating to the nervous system such as ataxia (inability to co-ordinate muscle movements) or tremor (shaking) may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site straight after treatment. In very rare cases there might also be some temporary itchiness, inflammation or hair loss at the place where the product has been applied to the cat's skin. These signs disappear without further treatment.

No side effects have been reported in dogs.

Profender should not be used in young animals (cats under 8 weeks of age or weighing less than 0.5 kg, or puppies under 12 weeks of age or weighing less than 1 kg).

As with other products of this type, Profender should be used on sick or ill cats or dogs only after a risk-benefit assessment by the vet. Profender should not be used for any other animal species.

Profender should not be allowed to enter surface water, as it may be harmful for aquatic organisms.

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

When giving Profender spot-on solution, skin contact with the pipette contents should be avoided and animals should not be stroked, groomed or allow to groom each other, until the application site is dry. The person giving the dose should not smoke, eat or drink, and should wash their hands thoroughly after use. If accidental exposure occurs, the eyes should be rinsed with water or the skin washed with soap and water.

The solvent in Profender spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces, so contact between the product and such surfaces should be avoided.

Users should also wash their hands after giving Profender as tablets to a dog.

Why is Profender approved?

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

Other information about Profender:

The European Commission granted a marketing authorisation valid throughout the EU for Profender on 27 July 2005.

The full EPAR for Profender 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 Profender, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2016.