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EPAR summary for the public

Prac-tic

Pyriple

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 Prac-tic?

Prac-tic is a spot-on solution that contains pyriple as active substance.

It is given to dogs with pre-filled spot-on pipettes, i.e. small plastic containers which are already filled with the correct amount of Prac-tic needed to treat one dog (Prac-tic is available in 4 different sizes for different dog sizes). For large dogs a combination of pipettes might be needed to achieve the correct dose. The content of the pipette is squeezed onto the skin after parting the fur in one up to three spots between the shoulder blades and down the backline of the dog.

What is Prac-tic used for?

Prac-tic is an "ectoparasiticide", which means that it will kill parasites that live on the skin or in the fur of animals, such as fleas and ticks.

Prac-tic is used to treat and to prevent tick and flea infestations in dogs. Once applied, it remains active for at least 4 weeks.

How does Prac-tic work?

Pyriple, interacts with a receptor involved in transmitting neural impulses (GABA receptor). This interferes with the nervous system of fleas or ticks and leads to the death of these parasites. Adult

fleas are killed before they lay eggs; since Prac-tic completely eliminates egg production, it breaks the flea life cycle.

How has Prac-tic been studied?

Data were provided on the pharmaceutical quality, the tolerance of the product in dogs and the safety in humans (people in contact with the product) and the environment.

The effectiveness of pyriprole against flea and tick infestations in dogs was investigated in laboratory studies and in field trials.

Two field studies were conducted in dogs at veterinary practices in several European countries and different geographic regions. Dogs from various breeds, age groups and weight that were infested with fleas or ticks were either treated with Prac-tic or with other products authorised in the EU for this indication. The effectiveness was measured looking at the number of live ticks or number of fleas at various times up to 3 months after application.

What benefit has Prac-tic shown during the studies?

The results of the field trials showed that Prac-tic is effective in the treatment and prevention of flea and tick infestations in dogs. The medicine killed fleas within 24 hours and ticks within 48 hours after treatment and its effectiveness lasted for at least 4 weeks.

What is the risk associated with Prac-tic?

The most common side effects in dogs are local reactions at the place where the product has been applied: change in the fur colour, hair loss and itchiness, as well as change in appearance of the fur (greasy appearance and clumpiness). If a dog licks the application area, the dog might salivate a lot for a short period.

Prac-tic should not be used in dogs less than 8 weeks old or less than 2 kg bodyweight since it has not sufficiently been studied in these animals. As other products of this group, Prac-tic should not be used in sick animals or dogs that have just recovered from illness. This product is specifically developed for dogs and should not be used in any other animal species.

Prac-tic 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?

As a precautionary measure, direct contact with the treated dog should be avoided and children should not be allowed to play with a treated animal until the application site is dry. Recently treated animals should not be allowed to sleep in the same bed as their owners, especially children.

People with known hypersensitivity to the phenylpyrazole class compounds or any of the excipients should avoid contact with Prac-tic.

Skin contact with the pipette content should be avoided. Skin should be washed and eyes should be rinsed with water, if accidental exposure occurred. When administering Prac-tic, the user should not smoke, eat or drink.

Why has Prac-tic been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Prac-tic exceed the risks for the approved indications and recommended that Prac-tic be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Prac-tic:

The European Commission granted a marketing authorisation valid throughout the European Union, for Prac-tic to on 18 December 2006. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in December 2012.