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EPAR summary for the public

Reconcile

fluoxetine

This is a summary of the European public assessment report (EPAR) for Reconcile. 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 Reconcile.

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

What is Reconcile and what is it used for?

Reconcile is a veterinary medicine used as an aid to treat dogs with behavioural problems caused by separation from their owners or homes or from other dogs (separation anxiety). Such problems may include destruction of property, excessive barking or howling and inappropriate defecation and urination in the home.

Reconcile should only be given in combination with behavioural therapy. It contains the active substance fluoxetine.

How is Reconcile used?

Reconcile is available as tablets (8, 16, 32 and 64 mg) and can only be obtained with a prescription. The tablet strength should be chosen according to the dog's weight. The tablets are given once a day.

Symptoms are expected to improve within 1 to 2 weeks. In case there is no improvement within 4 weeks, the veterinarian should re-evaluate treatment.

For further information, see the package leaflet.

How does Reconcile work?

Fluoxetine is an antidepressant. Fluoxetine works by increasing the levels of the neurotransmitter serotonin in the central nervous system. A neurotransmitter is a substance that nerve cells use to communicate with neighbouring cells. Since low levels of serotonin can be linked to depression and anxiety, increasing them can help dogs feel calmer so improving the behaviour in dogs with separation-related problems.



What benefits of Reconcile have been shown in studies?

A field study was conducted in a large number of dogs that were treated for separation anxiety in two European countries. All dogs received behavioural therapy and were treated either with Reconcile or with clomipramine (another medicine used to treat dogs with separation-related disorders). The main measure of effectiveness was the change in each of the nine different behaviours recognised as characteristic indicators of separation anxiety in dogs. The study showed that Reconcile was as effective as clomipramine. After 8 weeks of treatment, two separation anxiety behaviours were significantly improved in the Reconcile group (inappropriate defecation and destructive behaviour).

What are the risks associated with Reconcile?

The most common side effects with Reconcile (which may affect more than 1 in 10 dogs) are loss of appetite and lethargy (lack of energy). Other common side effects with Reconcile (which may affect up to 1 in 10 dogs) are urinary problems (inflammation of the bladder, lack of control in passing urine, inability to completely empty the bladder, and pain and difficulty in passing urine), and lack of coordination and disorientation.

Reconcile must not be given to dogs weighing less than 4 kg or to dogs with epilepsy or a history of fits. It must also not be used in dogs which are hypersensitive (allergic) to the active substance, any other ingredients or medicines in the same class as fluoxetine (serotonin-reuptake inhibitors).

For the full list of all side effects and restrictions reported with Reconcile, see the package leaflet.

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

If the product is accidentally swallowed by a person, the advice of a doctor should be sought immediately.

Why is Reconcile approved?

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

Other information about Reconcile?

The European Commission granted a marketing authorisation valid throughout the EU for Reconcile on 8 July 2008.

The full EPAR for Reconcile can be found on the Agency's website: [ema.europa.eu/Find/medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Veterinary%20medicines/European%20public%20assessment%20reports). For more information about treatment with Reconcile, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in August 2016.