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EPAR summary for the public

Clomicalm

clomipramine hydrochloride

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

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

What is Clomicalm and what is it used for?

Clomicalm is a veterinary medicine used as an aid in the treatment of dogs with behavioural problems when separated from their owners, their home or other dogs. Such problems may include destruction of property and inappropriate defaecation and urination in the home. Clomicalm should only be given in combination with behavioural therapy. It contains the active substance clomipramine hydrochloride.

How is Clomicalm used?

Clomicalm is available as tablets (5, 20 and 80 mg) and can only be obtained with a prescription. The appropriate strength tablet should be used according to the dog's weight. The tablets are given twice a day with or without food and usually 2 – 3 months is sufficient to control the condition although some dogs may need longer treatment.

How does Clomicalm work?

Clomipramine is an antidepressant. It works by increasing the levels of certain neurotransmitters, serotonin and noradrenaline, in the central nervous system. A neurotransmitter is a substance that relays signals from a nerve cell to another cell. Since low levels of these neurotransmitters can be linked to depression and anxiety, increasing them can help the dogs feel calmer so improving the behavioural signs in dogs with separation related problems.

What benefits of Clomicalm have been shown in studies?

Field studies conducted in the USA and Europe showed Clomicalm, when used with behavioural therapy,



to be effective in reducing behavioural problems in dogs associated with separation anxiety and was more effective than behavioural therapy alone on the basis of a broad spectrum of behavioural signs of anxiety including signs of high attachment to the owner.

What are the risks associated with Clomicalm?

Clomicalm may very rarely cause vomiting, changes in appetite, lethargy (lack of energy) or an elevation in liver enzymes which is reversible when treatment is stopped. Liver effects have been reported particularly in dogs with existing liver problems. Vomiting may be reduced by giving the tablets with a small quantity of food. Clomicalm must not be used in dogs with a known hypersensitivity to clomipramine and related medicines (known as tricyclic antidepressants).

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. If a child accidentally swallows the medicine, this could cause serious reactions.

Why is Clomicalm approved?

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

Other information about Clomicalm:

The European Commission granted a marketing authorisation valid throughout the EU for Clomicalm on 1 April 1998.

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

This summary was last updated in April 2016.