

EMA/790616/2018
EMA/V/C/004345

Isemid (*torasemide*)

An overview of Isemid and why it is authorised in the EU

What is Isemid and what is it used for?

Isemid is a veterinary medicine used to treat signs related to congestive heart failure in dogs. Congestive heart failure is a condition when the heart cannot pump enough blood around the body. This can lead to exercise intolerance (inability to carry out physical activity), difficulty breathing and fluid retention. Isemid contains the active substance torasemide.

How is Isemid used?

Isemid is available as tablets and can only be obtained with a prescription. It is given once daily and the starting dose depends on bodyweight. The tablet can be given with food or directly into the mouth if the dog does not take it easily. The usual dose is 0.13 to 0.25 mg torasemide per kg bodyweight once daily. This may be increased for up to 5 days to a maximum of 0.4 mg per kg bodyweight once daily in dogs with moderate to severe fluid retention in the lungs. The dose is then reduced and adjusted according to the dog's response.

For more information about using Isemid, see the package leaflet or contact your veterinarian or pharmacist.

How does Isemid work?

Torasemide is a diuretic medicine. It works by increasing the loss of water and salt in the urine. This decreases the overall blood volume, reducing the effort needed for the heart to pump blood and thereby improving its function.

What benefits of Isemid have been shown in studies?

In a field study involving 321 dogs with congestive heart failure, treatment with Isemid was compared with another established diuretic medicine, furosemide. The main measure of effectiveness was a reduction in scores for lung fluid and cough (both are signs of congestive heart failure) after 14 days of treatment and no worsening of difficulty in breathing or exercise intolerance scores. The study showed

Isemid to be as least as effective as furosemide for the treatment of signs related to congestive heart failure with 74% of dogs in each group being successfully treated.

What are the risks associated with Isemid?

The most common side effects with Isemid (which may affect more than 1 in 10 animals) are poor function of the kidneys, alterations in blood tests measuring kidney function, haemoconcentration (increase in the concentration of red blood cells circulating in the blood), and changes in electrolyte (salt) levels (chloride, sodium, potassium, phosphorus, magnesium and calcium).

Isemid must not be given in cases of kidney failure, dehydration, a decrease in circulating blood volume or low blood pressure. Isemid must not be given at the same time as other diuretics which work in the same way as torasemide.

For the full list of side effects and restrictions of Isemid, see the package leaflet.

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

Isemid may increase urination, and lead to thirst, gut disturbances, low blood pressure and dehydration if ingested. Any part-used tablets should be returned to the blister pack and then to the original carton to keep them out of the reach of children. If the product is accidentally swallowed by a person, particularly by a child, the advice of a doctor should be sought immediately and the package leaflet or label shown to the doctor.

This medicine may also cause hypersensitivity (allergic) reactions. People who are hypersensitive to torasemide, sulfonamides or to any of the other ingredients in Isemid should avoid contact with the medicine. If symptoms of allergy occur, the advice of a doctor should be sought immediately and the package leaflet or label shown to the doctor.

Hands should be washed after handling the medicine.

Why is Isemid authorised in the EU?

The European Medicines Agency decided that Isemid's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Isemid

Isemid received a marketing authorisation valid throughout the EU on 09/01/2019.

Further information on Isemid can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/isemid.

This overview was last updated in November 2018.