



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Onsior (*robenacoxib*)

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

### What is Onsior and what is it used for?

Onsior is an anti-inflammatory veterinary medicine for use in cats and dogs to treat pain and inflammation.

In cats, Onsior tablets are used to treat pain and inflammation associated with acute (short term) and chronic (long term) musculoskeletal disorders (problems with the muscles and bones) and to reduce moderate pain and inflammation associated with orthopaedic (bone) surgery. The solution for injection is used to treat pain and inflammation associated with orthopaedic or soft tissue surgery, such as neutering.

In dogs, Onsior tablets are used to treat pain and inflammation associated with chronic osteoarthritis (a long-term disease causing pain and inflammation in the joints) and soft tissue surgery. The solution for injection is used to treat pain and inflammation associated with orthopaedic or soft tissue surgery.

Onsior contains the active substance robenacoxib.

### How is Onsior used?

Onsior is available as tablets in five different strengths (6 mg for cats and 5 mg, 10 mg, 20 mg, and 40 mg for dogs) and as a solution for injection (20 mg/ml for dogs and cats).

The tablets are given once a day at the same time every day and the dose varies depending on bodyweight and use. Treatment in cats is limited to six days for acute musculoskeletal disorders and longer term for chronic musculoskeletal disorders, with monitoring by the veterinarian. Treatment in dogs for osteoarthritis should be for as long as is needed. If Onsior is used in cats and dogs to treat pain and inflammation associated with surgery, a single dose by mouth should be given before surgery. After surgery, a daily dose may be given for up to two further days.

The solution for injection is given as an injection under the skin to the animal around 30 minutes before the start of the operation at a dose based on the animal's bodyweight. After surgery in cats and soft tissue surgery in dogs, once daily treatment may be continued at the same dosage and at the same time every day for up to 2 days.

In dogs and cats, the tablets and the solution for injection can be used interchangeably respecting the approved uses and doses for each form.

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

### **How does Onsior work?**

The active substance in Onsior, robenacoxib, belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It works by blocking an enzyme called cyclooxygenase 2 (COX-2). This enzyme is involved in producing substances called prostaglandins, which are involved in pain and inflammation. By blocking the production of prostaglandins, robenacoxib reduces the pain and inflammation caused by musculoskeletal disorders, surgery or osteoarthritis.

### **What benefits of Onsior have been shown in studies?**

Onsior tablets given once a day reduced pain and improved mobility in both cats and dogs. Onsior was as effective as the comparator NSAIDs. In a clinical study, Onsior tablets increased the activity in 10 of 35 cats with chronic musculoskeletal disorders (as measured by activity monitors on a neck collar) and scores of behaviour, quality of life, temperament and apparent happiness of cats compared to placebo (a dummy treatment). In cats, Onsior tablets reduced moderate pain and inflammation associated with orthopaedic surgery for up to 2 days post operation when compared to animals that received placebo.

The solution for injection caused a gradual decrease in pain scores in cats and dogs after surgery. Pain was assessed by the veterinarian based on the animal's behaviour and responses to touching the inflamed area or moving the affected joint. After the end of the operation, sufficient pain control was seen up to 24 hours in dogs and up to 52 hours (2 days) in cats. Onsior was as effective as the comparator NSAIDs and more effective than placebo.

In a study involving dogs needing soft tissue surgery, daily treatment with Onsior tablets for 3 days afterwards reduced pain scores better than placebo.

### **What are the risks associated with Onsior?**

The side effects of Onsior are similar to those seen with other NSAIDs. The most common side effects of the tablets and solution for injection are mild and transient effects on the stomach and gut, seen as vomiting, soft faeces and diarrhoea. In dogs, an increase in liver enzymes after long-term treatment with the tablets is common (which may affect up to 1 in 10 animals). In very rare cases, lethargy may be observed.

The solution for injection can also cause pain on injection. For a full list of side effects of Onsior, see the package leaflet.

Onsior tablets must not be used in dogs or cats with existing problems affecting the stomach and gut, such as stomach ulcers or bleeding, or in dogs with liver problems. It must not be used in animals that are pregnant, nursing puppies or kittens or being used for breeding, or that are hypersensitive (allergic) to robenacoxib or any of the other ingredients. Care should be taken when treating cats or dogs with known heart or kidney problems, animals that are dehydrated and cats with liver problems. Onsior must not be used with other NSAIDs or with glucocorticosteroids.

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

Hands should be washed after giving the medicine to a dog or cat.

If the tablets are accidentally swallowed by a person, in particular by small children, or self-injection occurs with the solution for injection, the advice of a doctor should be sought immediately.

For pregnant women, particularly those in the later stages of pregnancy, prolonged skin contact with Onsior or accidental self-injection of Onsior might be dangerous for the unborn child.

### **Why is Onsior authorised in the EU?**

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

### **Other information about Onsior**

Onsior received a marketing authorisation valid throughout the EU on 16 December 2008.

Further information on Onsior can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPAR/onsior](http://ema.europa.eu/medicines/veterinary/EPAR/onsior).

This overview was last updated in December 2019.