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EPAR summary for the public

Zubrin

Tepoxalin

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the 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 Zubrin?

Zubrin is an oral lyophilisate, i.e. a kind of tablet that will quickly disintegrate upon contact with moisture e.g. when placed on your dog's tongue. Zubrin contains the active substance tepoxalin.

What is Zubrin used for?

Zubrin is used in dogs to reduce inflammation and relief of pain caused by acute and chronic musculoskeletal disorders.

Zubrin is given to the dog once a day within 1-2 hours after feeding until the dog gets better. However, since side effects might occur, any treatment exceeding 1 – 2 weeks should be under regular veterinary supervision.

How does Zubrin work?

Zubrin contains tepoxalin, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Zubrin acts by blocking enzymes, cyclooxygenase-1 and cyclooxygenase-2. When these enzymes are blocked, less prostaglandin is produced. As the

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prostaglandins are substances that trigger inflammation, tepoxalin reduces the inflammation and the swelling of muscles or joints and the pain associated with this.

How has the effectiveness of Zubrin been studied?

Zubrin has been studied in laboratory animals, as well as in dogs that were treated in various veterinary practices/clinics in the USA and in a number of countries in Europe ("clinical studies"). In these clinical studies, the animal owners gave Zubrin to their dogs, once daily at a dose of 10 mg per kg dog's bodyweight with or without food. The best results were achieved when Zubrin was adminstered 1-2 hours after feeding. The animals were treated until they got better; however, since side effects might occur, any treatment exceeding 1 – 2 weeks should be under regular veterinary supervision. Zubrin was as effective as other medicines of the same class and showed significant improvement in dogs with muscle or joint disease.

What are the side effects of Zubrin?

The side effects of Zubrin are those seen with other NSAIDs, such as vomiting, soft faeces or diarrhoea, blood in faeces, reduced appetite and tiredness. Vomiting or diarrhoea has been observed in one out of 10 dogs. In rare cases, particularly in older or in sensitive dogs, these effects may become very serious. Occasionally, loss of hair or red patches on the skin might occurr.

When such undesirable effects are seen in the dog, you should discontinue giving Zubrin to your dog. Also, before you start using Zubrin, inform the veterinarian if your dog receives any other medication since some medicines might influence each other's effectiveness.

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

Zubrin has a special pharmaceutical form (lyophilisate) that will quickly dissolve upon contact with moisture and might get very slippery or sticky when kept in your fingers. Therefore, you should make sure to administer the medicine with dry hands. If the lyophilisate disintegrates prematurely in your hands, wash your hands thoroughly.

Zubrin should be placed directly into the dog's mouth and you should try to keep the mouth of the dog closed for a short while.

Zubrin should not be used in people. However, if a number of tablets are accidentially consumed by a person, the advice of a doctor should be sought immediately.

Why has Zubrin been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Zubrin are greater than any risks when treating inflammation or pain in muscles or joints in dogs and they recommended that Zubrin should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Zubrin:

The European Commission granted a marketing authorisation valid throughout the European Union, for Zubrin on 13 March 2001. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated in January 2012.