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EPAR summary for the public

TruScient

dibotermin alfa

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (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 TruScient?

TruScient is a medicine that contains the active substance dibotermin alfa. TruScient is available as a kit for implant. The kit allows the user to make a solution containing the active substance (0.2 mg/ml) to be applied onto collagen sponges which are implanted during surgery.

TruScient has been developed for use in dogs based on the approved use of the InductOs product in humans (EU/1/02/226/001).

What is TruScient used for?

TruScient is used in combination with standard surgical care to treat diaphyseal bone fractures (affecting the diaphysis, the main section of long bone) in dogs. TruScient is made up into a solution before use, applied to the collagen sponges and left for at least 15 minutes (but no more than two hours). The prepared collagen sponges are then cut, if needed, to the correct size before use. Only the amount of prepared sponge needed to cover the affected area of the bone should be used. The prepared collagen sponges are implanted during surgery by placing them directly onto the bone fracture and leaving them in place when the surgical wound is stitched up.

TruScient should only be used by a veterinarian.

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How does TruScient work?

The active substance in TruScient, dibotermin alfa, acts on the bone structure. It is a copy of a protein called 'bone morphogenetic protein 2' (BMP-2), which is produced naturally by the body and helps with the formation of new bone tissue. When the collagen sponge is implanted into the bone fracture, dibotermin alfa stimulates the bone tissue around the sponge to make new bone. The newly formed bone grows into the collagen sponge, which then dissolves away. Dibotermin alfa is produced by a method known as 'recombinant DNA technology': it is made by cells that have received a gene (DNA) which makes them able to produce dibotermin alfa. The replacement dibotermin alfa acts in the same way as BMP-2 produced naturally by the body.

How has TruScient been studied?

TruScient was investigated in one main field study in 126 dogs with fractures of the diaphysis. The study assessed TruScient used together with standard surgical care, compared with standard surgical care alone. The main measure of effectiveness was the time until the fracture was seen to have healed using an X-ray (time to radiographic fracture healing).

What benefit has TruScient shown during the studies?

Time to radiographic fracture healing was less when the dogs were treated with TruScient together with standard surgical care. After 18 weeks, the fractures of all the dogs treated with TruScient together with standard surgical care (84) were seen to have healed, compared with 95% of the dogs treated with standard surgical care alone (40 out of 42).

What is the risk associated with TruScient?

The main side effects with TruScient (seen in more than 1 dog in 10) were lameness, and firm and soft swelling during the first three weeks after surgery. For a full list of all side effects reported with TruScient, see the package leaflet.

TruScient must not be used in dogs that are hypersensitive (allergic) to dibotermin alfa or any of the other ingredients. It must not be used in young dogs whose bones are not fully developed, have an active infection at the site of operation, pathological fracture (caused by a disease), or any active malignancy (cancerous growth).

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

If TruScient is accidentally spilled onto the skin or eyes, it should be rinsed off immediately.

Why has TruScient been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of TruScient exceed the risks for the treatment of diaphyseal bone fractures in dogs and recommended that TruScient be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about TruScient:

The European Commission granted a marketing authorisation valid throughout the European Union, for TruScient on 14 December 2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in April 2013.