



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Rabitec

rabies virus vaccine (live)

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

What is Rabitec and what is it used for?

Rabitec is a veterinary vaccine used to protect wild foxes and raccoon dogs against rabies. Rabies is a life threatening viral disease that causes inflammation in the brain. It presents a risk for people since it can be transmitted by bites or saliva from an infected animal. Rabitec contains a modified live rabies virus which has been weakened so that it does not cause disease.

How is Rabitec used?

Rabitec is available as a liquid (suspension) contained in a bait pellet scented with fish meal to be chewed. It can only be obtained with a prescription.

The baits are distributed by land or air and the vaccination area should be larger than 5,000 km². The number of baits distributed depends on the density of the fox and raccoon dog population and the nature of the vaccination area. Vaccination campaigns are conducted normally twice a year in spring and autumn for consecutive years, until at least 2 years after the last confirmed case of rabies in the area. To protect rabies free areas, vaccination may also be carried out at the border of these areas (vaccination belts) or in the form of spot vaccinations. Protection lasts at least 12 months after vaccination.

How does Rabitec work?

Rabitec is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Rabitec contains a weakened rabies virus that does not cause the disease. When a fox or raccoon dog chews a bait and the vaccine is released in the animal's mouth, the immune system recognises the virus as 'foreign' and makes defences against it. In the future, if

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animals are exposed to the rabies virus, the immune system will be able to respond more quickly, which will help to protect against the disease.

What benefits of Rabitec have been shown in studies?

Laboratory studies showed that around 90% of foxes and raccoon dogs produce antibodies against the rabies virus within 15 days of eating the bait. The protection against the virus lasts at least 6 months.

What are the risks associated with Rabitec?

There are no known side effects. For the full list of restrictions, see the package leaflet.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Rabitec, including the appropriate precautions to be followed by healthcare professionals and people who handle the product or come into contact with it.

Appropriate measures should be taken to prevent contamination such as wearing protective clothes and disposable rubber gloves, since the vaccine has been prepared with modified live virus. The baits should be handled with care. In case of skin or eye contact with the vaccine fluid the affected area should be rinsed immediately with water. Medical advice should be sought immediately and the package leaflet or label shown to the doctor, who should follow WHO recommendations for rabies exposure.

Why is Rabitec approved?

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

Other information about Rabitec?

The European Commission granted a marketing authorisation valid throughout the EU for Rabitec on 1 December 2017.

The full EPAR for Rabitec can be found on the Agency's website: ema.europa.eu/en/medicines/veterinary/EPAR/rabitec. For more information about treatment with Rabitec, read the package leaflet.

This summary was last updated in 03-2020.