



EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

RABIGEN SAG2

EPAR summary for the public

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 Rabigen SAG2?

Rabigen SAG2 is a vaccine against rabies. It is presented as baits.

What is Rabigen SAG2 used for?

Rabigen SAG2 is used for the active immunisation of red foxes (*Vulpes vulpes*) and raccoon dogs (*Nyctereutes procyonoides*) to prevent infection by rabies virus. The baits are distributed by land or by air. The number of baits distributed depends on the number of foxes or raccoon dogs and varies between 13 and 20 per square kilometre. Rabigen SAG2 can only be used by authorised personnel within the framework of vaccination campaigns against rabies.

How does Rabigen SAG2 work?

Rabigen SAG2 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Rabigen contains live rabies viruses. The viruses have been selected because of their 'low virulence' (limited ability to cause the disease). The viruses are contained in a sachet within a bait matrix. As the foxes or raccoon dogs eat the bait, they get exposed to the viruses and make antibodies against them. If the foxes or raccoon dogs are then exposed to the rabies virus later in life, they do not become infected.

How has Rabigen SAG2 been studied?

Foxes

The distribution of almost four million baits of the product during the field trials over four years have been followed by an intensive surveillance of the vaccination areas.

Raccoon dogs

As raccoon dogs are considered a minor species, no field trials were carried out. Efficacy was based on the efficacy results from laboratory studies and the extensive use of the vaccine in the field for foxes.

What benefit has Rabigen SAG2 shown during the studies?

When distributed in the wild, the SAG2 rabies vaccine bait was readily taken by free ranging foxes and raccoon dogs. Following bait uptake, adult and fox cubs and raccoon dogs showed significant antibody response. As a result, rabies decreased significantly in the vaccinated areas until its complete elimination. Moreover, the use of this vaccine has been efficiently preventing the vaccinated area from re-infection from still contaminated neighbouring areas. No case of vaccine induced rabies was reported, confirming the safety of the vaccine in the field. The vaccine confers 6-month protection against rabies.

What is the risk associated with Rabigen SAG2?

No undesirable effects have been shown for Rabigen SAG2.

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

It is recommended to wear rubber gloves when handling the bait. People handling and distributing this vaccine should be vaccinated against rabies. People whose immune system is weakened must not be allowed to handle this vaccine.

In the event of human exposure to the active substance of the vaccine, seek medical advice immediately and show the package leaflet or the label to the doctor.

Why has Rabigen SAG2 been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Rabigen SAG2 exceed the risks for its use in red foxes and raccoon dogs to prevent infection by rabies virus and recommended that Rabigen SAG2 be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Rabigen SAG2:

The European Commission granted a marketing authorisation valid throughout the European Union, for Rabigen SAG2 to Virbac S.A. on 6 April 2000. The marketing authorisation was subsequently renewed in 2005 and varied in April 2008 to include raccoon dogs as a new target species. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in May 2008.