



EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ADVASURE

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 Advasure?

Advasure is an emulsion for injection. Advasure contains a minimum of 32 µg of the active substance E2 glycoprotein of Classical Swine Fever (CSF) virus.

What is Advasure used for?

Advasure is used to immunise pigs from the age of 2 weeks onwards to prevent death and to reduce clinical signs of Classical Swine Fever (CSF). It is also used to reduce infection with CSF and excretion of CSF virus into the environment.

In emergencies, one dose (2 ml) of the vaccine may be given by intramuscular (into a muscle) injection close behind the ear. Depending on the severity of the infection and the disease, sows and piglets over the age of 2 weeks may be vaccinated twice with one dose (2 ml), 4–6 weeks apart. This does not depend on whether the pigs have any antibodies to CSF that have been passed on by their mother (maternal antibodies). For fattening pigs over the age of 10 weeks, just one injection with one dose is given. The pigs may be re-vaccinated every 6 months. Protection from CSF starts after 2 weeks and lasts for 6 months.

It is strongly recommended to vaccinate all pigs in the herd.

How does Advasure work?

Advasure contains an antigen – E2 (a substance that stimulates an immune response) to CSF. When this antigen is injected, this small exposure helps the pig's immune system to recognise and attack CSF. When exposed to CSF later in life, the pig will either not become infected or have a much less serious infection.

How has the effectiveness of Advasure been studied?

Very limited field studies were conducted with Advasure as CSF is a notifiable disease and safety studies were conducted to assess tolerance to the vaccine and local reactions. All studies except one were laboratory based.

Advasure has been studied in a large number of pigs using both a single or double vaccination. These studies included sows and gilts aged up to 40 months and also very young piglets with or without maternal antibodies. Advasure was also studied in fattening pigs where a single vaccination was given at age 10 weeks. The main measure of effectiveness was the production of antibodies to the CSF virus.

What benefit has Advasure shown during the studies?

Sows and gilts responded to both single and double vaccination with Advasure and developed enough antibodies for immunity for more than 6 months. Fattening pigs injected at 10 weeks also responded to a single vaccination and maintained their immunity for 3 months. Piglets vaccinated once at 2 weeks responded whether or not they had maternal antibodies and maintained their immunity for 24 weeks. Piglets given the double vaccination had higher levels of antibodies and the recommendation to vaccinate twice is justified.

What is the risk associated with Advasure?

Advasure can cause a swelling at the injection site, particularly in very young piglets, which usually disappears after one week. There may be a slight increase in body temperature. In very rare cases diarrhoea, anorexia (not eating), depression and vomiting may occur, which may need treatment if serious. Mild to moderate granulomas (small nodules) or abscesses may occur in the muscle tissue at the injection site. Although not reported so far, very rarely cases of allergic reactions may occur, so vaccinated pigs should be observed for about 30 minutes after vaccination. In case of a reaction, appropriate treatment should be given.

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

Advasure contains mineral oil. Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger – rarely causing the loss of a finger. If someone is accidentally injected with this product, they must seek immediate medical advice even if only a very small amount is injected. The package leaflet should be taken to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

Why has Advasure been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Advasure are greater than any risks for the purpose of immunising pigs from the age of 2 weeks onwards to prevent death and to reduce clinical signs of Classical Swine Fever. They recommended that Advasure should be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Advasure:

The European Commission granted a marketing authorisation valid throughout the European Union for Advasure (previously called Bayovac CSF E2) on 2 February 2001 and the current marketing authorisation holder is Pfizer Ltd. The marketing authorisation was renewed in February 2006.

The import, sale, supply and/or use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of CSF (Council Directive 80/217/EEC, as amended). Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorised by the competent authority of the Member State.

This summary was last updated in December 2006.