European Medicines Agency
Veterinary Medicines

EMEA/V/C/130

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

STARTVAC

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 Startvac?

Startvac is a vaccine for cows that contains inactivated (killed) bacteria called *Escherichia coli* and *Staphylococcus aureus*. Startvac is an emulsion for injection that is available in vials (3, 10 and 50 ml).

What is Startvac used for?

Startvac is used to strengthen the immunity of whole herds of otherwise healthy dairy cows in herds that are known to have problems due to mastitis (inflammation of the udder due to infection). The strengthened immunity reduces the number of cows affected and the severity of clinical signs.

Startvac is given to all healthy cows in a herd, during and after pregnancy. It is given as three injections into the neck muscle: the first is given 45 days before the cow is expected to give birth, the second 35 days later, and the third after another 62 days. The full course of injections should be repeated for every pregnancy.

How does Startvac work?

Startvac is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Startvac contains killed forms of two bacteria that normally cause mastitis (*Escherichia coli* and *Staphylococcus aureus*). When it is given to a cow, the animal's immune system recognises the bacteria as 'foreign' and makes antibodies against them. In the future, the immune system will be able to make the antibodies more quickly when it is exposed to the bacteria again. The antibodies will help to fight the bacteria, preventing mastitis occurring or reducing the severity of its symptoms.

The vaccine also contains an 'adjuvant' (liquid paraffin) to stimulate a better response.

How has Startvac been studied?

The company has carried out a number of studies, including one main study that looked at the effectiveness of Startvac in dairy cows under field conditions. The study compared cows that were given Startvac with those that were given placebo (a dummy vaccine) and looked at the number of cows with mastitis, the severity of mastitis symptoms, and milk production.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu
©EMEA 2009 Reproduction and/or distribution of this document is authorised for non commercial purposes only provided the EMEA is acknowledged

What benefit has Startvac shown during the studies?

The studies showed that Startvac reduced the number of cows with mastitis due to *Staphylococcus aureus* and related bacteria and it reduced the severity of the symptoms in the cows that had mastitis. Vaccination with Startvac also led to an increased number of cows being cured of the infection, a reduction in the number of cows that needed treatment for mastitis, and an increase in the quantity and quality of milk production.
Startvac injections did not have any harmful effects on pregnancy or giving birth, or on the cows' calves.

What is the risk associated with Startvac?

The vaccine may cause temporary swelling and pain at the site of injection. It may also cause a temporary increase in body temperature.

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

Startvac contains liquid paraffin (a type of mineral oil). Accidental injection or self-injection could cause severe pain and swelling, particularly if the vaccine is injected into a joint or finger. In rare cases, this could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek medical advice promptly, even if only a very small amount is injected, and take the Package Leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

The withdrawal period is zero days. The animal can be slaughtered for food at any time after injection.

What is the time to allow before milk can be taken from the animal for human consumption?

Milk can be taken at any time after injection.

Why has Startvac been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Startvac exceed the risks for herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and severity of the clinical signs of clinical mastitis caused by *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci, and recommended that Startvac be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Startvac:

The European Commission granted a marketing authorisation valid throughout the European Union, for Startvac to Laboratorios Hipra, S.A. on 11 February 2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 11 February 2009.

©EMEA 2009