

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NOBIVAC PIRO

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 Nobivac Piro?

Nobivac Piro is a vaccine that contains antigens (proteins) from the parasites *Babesia canis* and *Babesia rossi*. Nobivac Piro is a lyophilisate (freeze-dried pellet) and solvent that are made up into a suspension for injection.

What is Nobivac Piro used for?

Nobivac Piro is used to vaccinate dogs aged six months or older against *B. canis*, a protozoan (single-celled organism) transmitted by ticks that lives in red blood cells. The vaccine can reduce the severity of symptoms caused by acute (short-lived) babesiosis (the disease caused by infection with *B. canis*, with weakness, fever and jaundice) and anaemia (low red blood cell counts).

For initial vaccination, Nobivac Piro is given as two 1-ml injections under the skin three to six weeks apart. Re-vaccination is achieved with a single injection every six months. Immunity starts three weeks after the vaccination course and lasts for at least six months.

Only healthy dogs should be vaccinated. Dogs that are infected with *B. canis* but have no symptoms should be treated appropriately before vaccination. It is recommended that the vaccination is given at least one month before the tick season and exposure to ticks be reduced during the vaccination period.

How does Nobivac Piro work?

Nobivac Piro is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Nobivac Piro contains small amounts of antigens (soluble parasite antigens) from *B. canis* and the related species *B. rossi* that have been extracted from cultures of the parasites in red blood cells. The vaccine also contains an 'adjuvant' (a compound called saponin) to stimulate a better response. When a dog is given the vaccine, the immune system recognises the antigens as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is again exposed to *B. canis*. This helps to reduce the symptoms of babesiosis. Because the antigens on *B. canis* are very variable, vaccines against *B. canis* only work effectively if they also include antigens from *B. rossi*.

How has Nobivac Piro been studied?

The effectiveness of Nobivac Piro has been studied in three laboratory studies in which dogs were vaccinated and then challenged (exposed to wild type Babesia). Further one main field study was performed, including dogs of at least six months of age of various breeds who received two injections of Nobivac Piro three weeks apart. The effects of vaccination were compared with those of vaccination using a placebo (a dummy treatment). The main measure of effectiveness was the proportion of the dogs that developed antibodies against *B. canis* and *B. rossi* two weeks after the second injection.

What benefit has Nobivac Piro shown during the studies?

Nobivac Piro was more effective than placebo at stimulating the production of antibodies: more dogs receiving the vaccine developed antibodies than those receiving placebo.

What is the risk associated with Nobivac Piro?

After vaccination, painful swelling or hardened nodules occur commonly at the site of vaccination. In general, these disappear within four days, but in rare cases they can persist for up to 14 days after the second injection. Side effects such as lethargy (listlessness) and a reduction in appetite are also common, sometimes accompanied by fever and a stiff gait. These reactions should disappear within two to three days.

Vaccination with Nobivac Piro does not prevent infection, so a milder form of disease caused by *B. canis* can occur. If mild symptoms occur and last for more than two days, veterinary advice should be sought.

Nobivac Piro should not be used in bitches that are pregnant or lactating.

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

If accidental self-injection occurs, seek medical advice immediately and show the Package Leaflet or the label to the doctor.

Why has Nobivac Piro been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Nobivac Piro exceed the risks for active immunisation of dogs of six months or older against *B. canis* to reduce the severity of clinical signs associated with acute babesiosis (*B. canis*) and anaemia as measured by packed cell volume, and recommended that Nobivac Piro be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Nobivac Piro:

The European Commission granted a marketing authorisation valid throughout the European Union for Nobivac Piro to Intervet International B.V. on 2 September 2004. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 30 August 2007.