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EPAR summary for the public

Parvoduk

Muscovy duck parvovirus (live attenuated)

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 Parvoduk?

Parvoduk is a veterinary vaccine that contains live attenuated (weakened) Muscovy duck parvovirus. It contains a strain called GM 199. Parvoduk is available as a suspension and diluent for injection.

What is Parvoduk used for?

Parvoduk is used to protect Muscovy ducks against Muscovy duck parvovirosis and Derzsy's disease. Muscovy duck parvovirosis is an infectious disease caused by Muscovy duck parvovirus. Week-old ducklings show a range of signs including death and muscle weakness whilst older ducklings display stunted growth, nervous symptoms and feather abnormalities. Derzsy's disease is a similar infection caused by the closely related virus, goose parvovirus.

The vaccine is given to day-old ducklings as an injection under the skin, repeated after 16 days.

How does Parvoduk work?

Parvoduk is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The Muscovy duck parvovirus in Parvoduk is alive but it has been attenuated (weakened) so that it does not cause disease. When Parvoduk is given to Muscovy ducks the animals' immune system recognises the viruses as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to Muscovy duck parvovirus, the immune system will

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be able to respond more quickly. This will help protect them against Muscovy duck parvovirosis. Because goose parvovirus is very similar to Muscovy duck parvovirus, the immune response also provides protection if the animal is exposed to goose parvovirus.

How has Parvoduk been studied?

The effectiveness of Parvoduk was investigated in laboratory studies. One-day-old ducklings were given a single injection of Parvoduk and then exposed two weeks later to either Muscovy duck parvovirus or goose parvovirus. The measure of effectiveness was reduction in death rates, stunting of growth, feather abnormalities and damage to organs seen at post-mortem. Two further studies were carried out to investigate the effects of Parvoduk in ducklings who had inherited protective antibodies against Muscovy duck parvovirus or goose parvovirus from their mother.

No field studies were conducted. This was considered acceptable, given the laboratory data and taking into account that the Muscovy duck is a minor species.

What benefit has Parvoduk shown during the studies?

The laboratory studies showed that, two weeks after vaccination, Parvoduk prevented deaths in the ducklings and reduced damage to organs. Growth after exposure to Muscovy duck parvovirus or goose parvovirus was improved in vaccinated ducklings by 70% and 110%, respectively. The further study showed that Parvoduk vaccination of ducklings was not counteracted by protective antibodies from their mother. In addition it was shown that Parvoduk remains effective until the ducklings are aged six weeks, which means that the ducklings are protected during the period when they are at risk of Muscovy duck parvovirosis and Derzsy's disease.

What is the risk associated with Parvoduk?

Although the weakened virus in Parvoduk has not been shown to pass between birds or to cause disease, all the ducklings in a flock should be vaccinated to reduce the risk of this happening. No side effects have been reported to date.

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

None.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption or eggs or milk used for human consumption. The withdrawal period for Parvoduk is zero days.

Why has Parvoduk been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Parvoduk exceed the risks for the approved indication and recommended that Parvoduk be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Parvoduk:

The European Commission granted a marketing authorisation valid throughout the European Union, for Parvoduk on 11/04/2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in February 2014.