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Clynav (*salmon pancreas disease vaccine (recombinant DNA plasmid)*)

An overview of Clynav and why it is authorised in the EU

What is Clynav and what is it used for?

Clynav is a veterinary vaccine used to protect Atlantic salmon against pancreas disease caused by salmonid alphavirus subtype 3 (SAV3). Pancreas disease in Atlantic salmon can reduce weight gain, leads to damage of the heart, pancreas and skeletal muscle, and may cause death.

The active substance in Clynav is a DNA plasmid (a small piece of DNA) containing the genetic code for making proteins found in salmon pancreas disease virus (SPDV).

How is Clynav used?

Clynav is available as a solution for injection and can only be obtained with a prescription.

The vaccine is given to anaesthetised fish as a single injection into epaxial muscle (muscle of the upper half of the fish) in the area to the front and side of the dorsal fin. The time for protection to develop after vaccination depends on the water temperature: protection starts within 399 degree days, calculated as mean water temperature in °C multiplied by number of days; for example, 40 days at a water temperature of 10°C. Protection lasts about 12 months after vaccination for improved weight gain and reduced damage to heart, pancreas and skeletal muscle, and 9½ months for reduced mortality.

For more information about using Clynav, see the package leaflet or contact your veterinarian or pharmacist.

How does Clynav work?

Clynav is a DNA vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend against an infectious disease. Clynav contains a DNA plasmid which, once injected into fish, will lead to the production of proteins found in SPDV. The immune system recognises these virus proteins as 'foreign' and makes defences against them. In future, if the fish come into contact with the virus, the immune system will be ready to defend against the virus quickly. This will help to protect against the disease.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Clynav have been shown in studies?

Seven laboratory studies in fresh water and sea water showed that the vaccine was effective for protecting salmon from disease caused by SPDV. A laboratory study looked at the signs of pancreas disease in fish given Clynav compared with fish given a dummy saline (salt solution) injection. Following artificial infection by co-habitation with infected salmon in saltwater conditions 29 days after vaccination as well as after 6, 9½ and 12 months, fish vaccinated with Clynav had improved weight gain and reduced damage to heart, pancreas and skeletal muscle compared with fish injected with the dummy saline injection. The risk of death was reduced at 9½ months after vaccination compared with fish injected with the dummy saline injection.

What are the risks associated with Clynav?

The most common side effects with Clynav (which may affect more than 1 in 10 animals) are changes in swimming behaviour for up to two days, altered pigmentation (colouration) for up to seven days and lack of appetite for up to nine days. Needle injuries at the site of injection are common and can last for at least 90 days.

For the full list of side effects of Clynav, see the package leaflet.

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

Direct contact should be avoided and protective equipment (for example protective gloves) should be worn when handling the medicine.

In case of accidental needle stick or self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for fish from Atlantic salmon treated with Clynav is 'zero' days, which means there is no mandatory waiting time.

Why is Clynav authorised in the EU?

The European Medicines Agency decided that Clynav's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Clynav:

Clynav received a marketing authorisation valid throughout the EU on 27 June 2017.

Further information on Clynav can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/clynav.

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