Exzolt
fluralaner

This is a summary of the European public assessment report (EPAR) for Exzolt. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Exzolt.

For practical information about using Exzolt, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Exzolt and what is it used for?

Exzolt is a veterinary medicine used to treat poultry red mite (Dermanyssus gallinae) infestation in pullets (young female chickens), breeders and layer hens. Poultry red mite is a parasite that feeds on the blood of hens. Red mite infestations can cause irritation and restlessness of the bird, feather pecking and anaemia (low red blood cell counts). Egg production may also be affected. Exzolt contains the active substance fluralaner.

How is Exzolt used?

Exzolt is available as a solution for use in drinking water and can only be obtained with a prescription. Exzolt is added to drinking water on two occasions, seven days apart. Sufficient Exzolt is added to ensure the required dose is present in the volume of water that the chickens will consume in one day. If another course of treatment is required, the interval between the two courses of treatment should be at least 3 months.

For further information, see the package leaflet.

How does Exzolt work?

The active substance in Exzolt, fluralaner, acts as an ‘ectoparasiticide’. This means it kills parasites such as mites that feed on the skin of animals. Fluralaner kills mites by acting on their nervous system after they have ingested the chicken’s blood. It works by interfering with the way that signals are
passed between nerve cells (neurotransmission) in the nervous system of parasites, resulting in paralysis and death of the mites.

**What benefits of Exzolt have been shown in studies?**

Exzolt has been studied in a field study involving 9 farms with poultry red mite infestation, each with two similar houses with 550 to 100,000 chickens per house. One of the houses on each of the farms was treated with Exzolt, the other house was left untreated. Exzolt reduced the number of mites by more than 99% in pullets and breeders and more than 98% in layers. The duration of effectiveness was between 6 weeks and 8 months, depending on the length of the production cycle and how effectively the farms prevented re-introduction of new mites into their houses.

**What are the risks associated with Exzolt?**

There are no known side effects. For the full list of restrictions, see the package leaflet.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Exzolt, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

Since the veterinary medicine may be slightly irritating to skin and/or eyes, contact with skin, eyes and mucous membranes (moist body surfaces, such as the lining of the mouth) should be avoided. While handling the product people must not eat, drink or smoke. Hands and contacted skin should be washed after use of the medicine.

**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. It is also the time required after administration of a medicine before eggs may be used for human consumption.

The withdrawal period for meat from chickens treated with Exzolt is 14 days.

The withdrawal period for eggs from chickens treated with Exzolt is 'zero' days, which means there is no mandatory waiting time.

**Why is Exzolt approved?**

The Agency’s Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Exzolt’s benefits are greater than its risks and recommended that it be approved for use in the EU.

**Other information about Exzolt?**

The European Commission granted a marketing authorisation valid throughout the EU for Exzolt on 18 August 2017.

The full EPAR for Exzolt can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Exzolt, animal owners or keepers should read the package leaflet or contact their
veterinarian or pharmacist.

This summary was last updated in June 2017.