



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/652030/2016
EMA/V/C/002723

EPAR summary for the public

VarroMed

oxalic acid dihydrate / formic acid

This is a summary of the European public assessment report (EPAR) for VarroMed. 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 VarroMed.

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

What is VarroMed and what is it used for?

VarroMed is a medicine used to treat varroosis in honey bee colonies. Varroosis is a disease of honey bees caused by infestation with a parasite called Varroa mite (*Varroa destructor*). The Varroa mite feeds on the haemolymph (blood) of adult bees and on brood (developing stages of the honey bee) resulting in damage and / or death of bees; the mite can also help spread of viruses and bacteria. A significant mite infestation can lead to the collapse of a honey bee colony. VarroMed can be used on colonies with and without brood.

VarroMed contains the active substances oxalic acid dihydrate and formic acid.

How is VarroMed used?

VarroMed is available as a bee-hive dispersion (a liquid for use inside the bee hive) and can be obtained without a prescription.

VarroMed is trickled onto bees in the brood chamber of the hive. The dose is adjusted to the colony size. VarroMed is intended to be used as part of an integrated varroa control programme, which includes other techniques. It can be used either as a single-dose treatment during the broodless period (winter treatment), or in the presence of brood (spring or autumn treatment) which will usually require repeated treatments. Treatment should be given in the late afternoon or evening when bees are less likely to be flying.

For further information, see the package leaflet.



How does VarroMed work?

How both oxalic acid and formic acid work is not well understood. The activity of oxalic acid on mites is thought to be due to the acidity of the medicine. Formic acid is thought to kill Varroa mites by blocking the ability of their cells to generate energy; it may also act on mite nerve cells.

What benefits of VarroMed have been shown in studies?

The effectiveness of VarroMed was investigated in field studies in European countries with different climates, both continental climate and Mediterranean climate. In each location 20 test groups were compared to 12 control groups treated with flumethrin (another medicine effective against parasites). The groups were treated during winter (in the absence of brood), spring and autumn (in the presence of brood) and included colonies of different sizes (5,000 to 30,000 bees) and different infestation levels. Varroa mite and honey bee mortality were monitored twice weekly for 4 weeks during treatment until one week after treatment. The average effectiveness of VarroMed to kill mites (measured by the number of dead mites found at the bottom of the hive) was 88% for winter, 92% for spring and 85% for autumn treatments.

What are the risks associated with VarroMed?

The most common side effect with VarroMed (which may affect more than 1 in 10 bee colonies) is an increased number of deaths of worker bees. This effect increases with higher doses and/or repeated treatments.

VarroMed must not be given during nectar flow, when honey is produced by bees, and should not be used when honey chambers are attached to the hive.

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

VarroMed is irritating to the skin and eyes. People should avoid contact with the skin, eyes and mucous membranes (moist body surfaces such as lining of mouth). In case of accidental spillage onto skin, the affected areas should be washed immediately with running water. In case of accidental spillage into the eye(s) flush the eye(s) immediately with clear running water for 10 minutes.

Children should be kept from contact with VarroMed. Accidental ingestion may cause adverse reactions.

Protective clothing, acid-resistant gloves and glasses should be worn during treatment. Heavily contaminated clothes should be changed immediately and washed before re-use.

People who are hypersensitive (allergic) to formic acid or oxalic acid should give the medicine with caution.

People must not eat, drink or smoke while using the medicine.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before honey may be used for human consumption.

The withdrawal period for honey from honey bees treated with VarroMed for is 'zero' days, which means there is no mandatory waiting time.

Why is VarroMed approved?

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

Other information about VarroMed?

The European Commission granted a marketing authorisation valid throughout the EU for VarroMed on 2 February 2017.

The full EPAR for VarroMed 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 VarroMed, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in October 2016.