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EPAR summary for the public

Velactis

cabergoline

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

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

What is Velactis and what is it used for?

Velactis is a medicine used in the herd management programme of dairy cows as an aid to reduce milk production in dairy cows at the start of the dry period (the period when the cow is not milked before calving and start of the next lactation). Velactis is used to:

- reduce milk leakage at drying off (the point at which the cow is no longer milked),
- reduce the risk of new infections of the udder during the dry period,
- reduce discomfort.

It contains the active substance cabergoline. For further information, see the package leaflet.

How is Velactis used?

The medicine can only be obtained with a prescription. Velactis is given as a single injection into the muscle within four hours of the last milking on the day of drying off. Velactis is available as a solution for injection in multidose vials of 5 ml, 25 ml or 50 ml.

How does Velactis work?

Milk production is stimulated by a hormone, prolactin, released from specialised cells in the pituitary

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

gland (a small gland attached to the brain). Cabergoline has a long-lasting action on receptors in these cells (called D2 receptors) that block release of the hormone. By blocking prolactin release in this way, milk production is reduced.

What benefits of Velactis have been shown in studies?

In an initial field study with 917 cows, Velactis was given to cows free of subclinical mastitis (inflammation of the udder without visible clinical signs) and in the absence of antimicrobial treatment, showed a 5.5% reduction of new udder infections during the dry period compared to cows treated with placebo (the dummy treatment). Velactis reduced the incidence of milk leakage to 2% compared to 10.7% in the cows treated with placebo.

In a second field study involving 263 dairy cows the percentage of Velactis-treated cows with milk leakages during a 14-day period after drying-off was 3.9% compared with 17.6% for the cows treated with placebo.

A third field study involved 228 dairy cows. Velactis treated cows showed reduced discomfort on the first day of drying-off as indicated by increased daily lying time.

What are the risks associated with Velactis?

The most common side effects with Velactis (which may affect up to 1 in 10 cows) are slight injection site reactions (mostly swellings) after injection of the product which may persist for at least 7 days.

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 Velactis, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

People who are hypersensitive (allergic) to cabergoline should avoid contact with Velactis.

Hands should be washed after handling the product.

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

Pregnant women and women attempting to conceive should avoid contact with Velactis. As Velactis reduces milk production, breastfeeding women should also avoid contact with the product.

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 milk may be used for human consumption.

The withdrawal period for meat from dairy cows treated with Velactis is 23 days.

The withdrawal period for milk from dairy cows treated with Velactis is ‘zero’ days, which means there is

no mandatory waiting time after calving, if the dry period length is 32 days or more. It is 4 days (8 milkings) after calving when the dry period length is less than 32 days.

Why is Velactis approved?

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

Other information about Velactis?

The European Commission granted a marketing authorisation valid throughout the EU for Velactis on 9 December 2015.

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

This summary was last updated in October 2015.