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EMA recommends suspending the veterinary medicine Velactis used in dairy cows at the time of drying off

Suspension follows reports of serious adverse events in cows, including recumbency and deaths

EMA's Committee for Medicinal Products for Veterinary Use (CVMP) has recommended suspending the marketing authorisation of Velactis (cabergoline), a veterinary medicine used to reduce milk production in dairy cows at the time of drying off, when milking is being stopped.

The recommendation follows reports of adverse events in 319 dairy cows after treatment with Velactis. Many of the adverse events were serious, including recumbency (lying down and being unable to stand) in 208 animals, which generally occurred within 24 hours of administering Velactis. In total, there were 71 reported deaths in cows, most after a period of recumbency.

Although the exact cause of these adverse events is yet to be determined, there is evidence to suggest that they may be linked to the use of Velactis. Given the number and severity of adverse events following use of the medicine in otherwise healthy dairy cows, the Committee concluded that, at present, the risks outweigh the benefits of the product.

The CVMP therefore recommended that the marketing authorisation for Velactis be suspended in the European Union (EU) until further information is available to show that the benefits outweigh the risks, possibly under new conditions of use or restrictions.

The Committee also recommended as a precautionary measure a recall of Velactis currently on the market in the EU. The use of the medicine has already been suspended by national authorities in some EU Member States and the company has informed EMA that it has suspended sales in the EU.

The CVMP's recommendations will now be sent to the European Commission for a legally binding decision applicable in all EU Member States.

Information for users

- Velactis is used as an aid in the abrupt drying-off in dairy cows and has been linked to several cases of recumbency and deaths.
- As a result of the serious cases, the authorisation of Velactis is being suspended.

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- Users are advised to stop using Velactis in dairy cows and use alternative methods for dry off.
- Users who have any questions should contact their veterinarian or national veterinary medicines authority.

More about the medicine

Velactis is for use in the management programme of dairy cows as an aid in the abrupt drying-off by reducing milk production to: reduce milk leakage at drying off, reduce the risk of new intramammary infections during the dry period, reduce discomfort.

It contains the active substance cabergoline and works by blocking the release of prolactin, the hormone that stimulates milk production.

Velactis was authorised centrally in the EU in December 2015. At the time of the CVMP recommendation for suspension, the medicine had been marketed in the following Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Luxemburg, The Netherlands, Poland, Portugal, Romania, Spain and United Kingdom.

The marketing authorisation holder for Velactis is CEVA Santé Animale.

More about the procedure

The review of Velactis was initiated on 16 June 2016 upon the request of the European Commission, under article 45 of Regulation (EC) No.726/2004.

The review was carried out by the Committee for Medicinal Products for Veterinary Use (CVMP), the EMA committee responsible for preparing opinions on questions concerning medicines for veterinary use, which has made a set of recommendations.

The CVMP recommendations will now be transmitted to the European Commission for the adoption of a legally binding decision applicable in all EU Member States.

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