Yondelis: review started

20.03.2020 | Circular Number P05/2020

Information on Yondelis

- Yondelis (trabectedin), is a cancer medicine used to treat ovarian cancer and soft-tissue sarcoma (a type of cancer that develops from the soft, supporting tissues of the body)
- For the treatment of ovarian cancer, Yondelis is used in association with pegylated liposomal doxorubicin to treat relapsing ovarian cancer (come back after previous treatment) which is sensitive to medicines containing platinum
- For the treatment of advanced soft-tissue sarcoma, Yondelis is used when the cancer starts to spread and anthracyclines and ifosfamide (other cancer medicines) have stopped working, or in patients who cannot be given these medicines.

In Malta Yondelis is authorised through a centralised procedure.

Information from the EMA about Yondelis for the treatment of ovarian cancer

The Committee for Medicinal Products for Human Use (CHMP) started a review on Yondelis (trabectedin) under Article 20 of Regulation (EC) No 726/2004, following the request of the European Commission. The review started following a clinical study (OVC-3006), investigating Yondelis for the treatment of ovarian cancer, which was stopped ahead of time. An interim analysis of the study results showed that overall, patients treated with Yondelis plus pegylated liposomal doxorubicin (PLD, another cancer medicine) did not live longer than patients given PLD alone.

Type of patients enrolled in study OVC-3006 were different from type of patients enrolled in the study which led to the authorisation of Yondelis but included patients for whom Yondelis would be indicated. Therefore, the EMA will review the available data to assess potential impact that results from OVC-3006 can have on the authorised use of Yondelis in patients with ovarian cancer.

The review will cover only the use of Yondelis for the treatment of ovarian cancer and not the use of Yondelis for the treatment of soft-tissue sarcoma. While the review is ongoing and according to the authorised product information, patient under the treatment of Yondelis can continue using it for both ovarian cancer and soft-tissue sarcoma. Patients who have any questions about their treatment should speak to their doctor.

The CHMP opinion will be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

For more information, visit the European Medicines Agency's Yondelis referral page

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Yondelis (trabectedin). Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
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Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

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