EUROPEAN MEDICINES AGENCY
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Press Office

Press release

European Medicines Agency recommends restricting the use of dexrazoxane-containing medicines

Medicines should be restricted in breast cancer patients and contraindicated in children and adolescents

The European Medicines Agency has recommended restricting the use of dexrazoxane to adult patients with advanced or metastatic breast cancer who have already received a certain amount of the anthracyclines doxorubicin and epirubicin to treat their cancer. The Agency's Committee for Medicinal Products for Human Use (CHMP) also recommended contraindicating the use of this medicine in children.

Dexrazoxane is currently indicated for use in patients with cancer to prevent long-term toxic effects on the heart caused by treatment with doxorubicin and epirubicin.

The review of dexrazoxane was initiated following concerns that it could be linked to an increased risk of acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS). This was based on studies in the United States reporting cases of AML and MSD in children as well as on a small number of cases of AML reported in adult breast cancer patients receiving dexrazoxane.

Following review of all available data, the Committee concluded that there was evidence of serious harm in children and adolescents receiving dexrazoxane and that the benefits of the medicine do not outweigh the risks in this age group. The Committee therefore recommended contraindicating dexrazoxane in patients under the age of 18.

With respect to the use of dexrazoxane in adults, the Committee concluded that the benefits of dexrazoxane only outweigh the risks in adult patients with advanced or metastatic breast cancer who have already received a minimum cumulative dose of 300 mg/m^2 of doxorubicin or 540 mg/m^2 of epirubicin. It also recommended that the use of dexrazoxane when used with doxorubicin should be reduced from a dose ratio of 20:1 (20 parts dexrozaxone to 1 part doxorubicin) to a ratio of 10:1. The dose ratio of dexrazoxane to epirubicin remains unchanged at 10:1. When deciding to use dexrazoxane, prescribers should carefully weigh the possible benefits in relation to the protection of the heart against the short- and long-term risks, particularly the risk of AML and MDS.

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The Committee's scientific recommendation has now been forwarded to the European Commission for the adoption of a decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Dexrazoxane is authorised in Austria, Czech Republic, Germany, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia Spain and the United Kingdom under the invented names Cardioxane, Cyrdanax, Dexrazoxane Cyathus, Enaxozar and Procard.
3. The review of dexrazoxane was carried out under Article 31 of the Community code relating to medicinal products for human use (Directive 2001/83/EC), as amended. This type of procedure foresees that the CHMP makes a recommendation on whether the marketing authorisation for a medicine should be maintained, changed, suspended or revoked.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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