

<Date>

Savene (dexrazoxane) 20 mg/ml powder and solvent for concentrate for solution for infusion: potential contamination risk affecting a limited number of batches

Dear Healthcare professional,

CNX Therapeutics Ireland in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following:

Summary

- **A potential risk of contamination affecting a limited number of batches of Savene has been identified. While the risk cannot be excluded, the probability of contamination is very low.**
- **The following batch numbers are impacted: B340A05, B340A01, B340A02 and B340A07.**
- **Prior to administration, visually inspect Savene vials for cloudiness or abnormal appearance; if such abnormalities are observed do not administer the product.**
- **Remain vigilant for signs of infection in patients who have already been treated with Savene.**

Background on the safety concern

Savene (dexrazoxane) is indicated in adults for the treatment of anthracycline extravasation.

Savene is available as an emergency kit consisting of 10 vials of Savene powder and 3 bottles of Savene solvent supplied with 3 bottle hangers. Before infusion, Savene powder must be reconstituted with 25 ml of Savene solvent to give a concentration of 20 mg dexrazoxane per ml. The concentrate is slightly yellow. The concentrate should then be diluted further in the remaining Savene solvent.

Caution must be exercised during reconstitution and dilution and the normal procedures for proper handling of cytotoxic medicinal products should be adopted.

CNX Therapeutics Ireland has identified a deviation during a quality investigation. For a limited number of batches, a potential contamination risk cannot be fully excluded which may affect the sterility of the product.

Based on the available information, the likelihood of contamination is considered very low. However, as Savene is administered intravenously and patients receiving Savene are immunocompromised, a theoretical risk of infection cannot be completely excluded.

Considering the very low likelihood of contamination and the critical therapeutic need for Savene, the benefit–risk balance supports maintaining availability of the affected batches.

As a precautionary measure, healthcare professionals are advised to

- Visually inspect Savene vials prior to administration for cloudiness or abnormal appearance and not administer the product if such abnormalities are observed.
- Monitor patients for signs of infection following Savene administration.

Call for reporting

Reporting suspected adverse reactions allows for continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions

via the national reporting system and include batch/Lot number if available. < include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system >

When reporting a suspected adverse reaction, please provide the name of the product associated with the event, as well as the lot number and the expiration date of the product.

Company contact point

< Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN

Medicinal product(s)/active substance(s) Savene (dexrazoxane) 20 mg/ml powder and solvent for concentrate for solution for infusion

Marketing authorisation holder(s) CNX Therapeutics Ireland Limited

Safety concern and purpose of the communication Potential contamination risk affecting a limited number of batches:

DHPC recipients HCPs involved in the prescribing, preparation and administration of Savene in hospital oncology settings:

- Oncologists
- Haematologists
- Hospital pharmacists and oncology pharmacists
- Oncology nurses and chemotherapy administration nurses
- Oncology treatment centres and hospital oncology departments

The target group should be further defined at national level, in agreement with the respective national competent authority.

Member States where the DHPC will be distributed

- Austria
- Belgium
- Denmark
- Finland
- France
- Germany
- Greece
- Ireland
- Italy
- Netherlands
- Norway
- Portugal
- Spain
- Sweden

Timetable**Date**

DHPC and communication plan (in English) agreed by CHMP/CMDh 26 March 2026

Submission of translated DHPCs to the national competent authorities for review 02 April 2026

Agreement of translations by national competent authorities 15 April 2026

Dissemination of DHPC 23 April 2026