6th February 2023

Supply shortage of Fasturtec® (rasburicase) 7.5 mg/5 ml powder and solvent for concentrate for solution for infusion (EU/1/00/170/002)

Direct Healthcare Professional Communication

Dear Healthcare Professional,

Sanofi, in agreement with the European Medicines Agency and the Medicines Authority, would like to inform you of the following important information about rasburicase.

Summary

- **In Malta, supply of Fasturtec® (rasburicase) 7.5 mg/5 ml presentation is expected to be constrained from March 31st, 2023 until July, 2024.**

- **If Fasturtec® (rasburicase) 7.5 mg/5 ml (pack size 1 vial + 1 ampoule of solvent) is not available, the 1.5 mg/1 ml presentation (pack size 3 vials + 3 ampoules of solvent) can be used instead** (the chemical and biological contents of the 7.5 mg and 1.5 mg vials are identical). In this case, the use of several vials may be necessary to obtain the quantity of rasburicase required for one administration (for the required reconstitution steps, please see below).
Switch to be adapted at the national level according to the local approved labeling and availability of the alternative presentation.

Background on the supply concern

- Fasturtec® (rasburicase) is a recombinant urate oxidase enzyme produced by genetically modified *Saccharomyces cerevisiae*.
- Fasturtec® (rasburicase) is approved for treatment and prophylaxis of acute hyperuricaemia, to prevent acute renal failure in adults, children and adolescents (aged 0 to 17 years) with haematological malignancy with a high tumor burden and at risk of rapid tumor lysis or shrinkage at initiation of chemotherapy.
- Two presentations are approved and marketed in your country (7.5 mg/5 ml and 1.5 mg/1 ml):
    - Supply constraint is expected for the 7.5 mg/5 ml presentation, due to a delay in manufacturing transfer;
    - the 1.5 mg/1 ml presentation is not impacted and remains available.
- Patients' health and safety is Sanofi's priority. Sanofi is working diligently to minimise the impact of supply disruption for this presentation, and we are committed to communicating proactively and in a timely manner as the situation evolves.

Recommendations for risk minimisation

As a reminder, please find below the appropriate preparation instructions in case a switch to the 1.5 mg presentation is necessary to ensure treatment continuity:

The correct preparation of the solution for infusion of Fasturtec requires two steps:

- Reconstitution of the solution:

Fasturtec must be reconstituted with the entire volume of the supplied solvent (1.5 mg rasburicase vial to be reconstituted with the 1 ml solvent ampoule). Reconstitution results in a solution with a concentration of 1.5 mg/ml.

- Dilution before infusion:

The required volume of the reconstituted solution depends on the patient's body weight (the recommended dose is 0.20 mg/kg/day). The use of several vials may be necessary to obtain the quantity of rasburicase required for one administration. The required volume of the reconstituted solution, taken from one or more vials, is to be further diluted with sodium chloride 9 mg/ml (0.9%) solution to make a total volume of 50 ml. The concentration of rasburicase in the final solution for infusion depends on the patient's body weight.

The reconstituted solution contains no preservative. Therefore, the diluted solution should be infused immediately, over 30 minutes.

In addition, and as general guidance, to minimise leak and dead volume during serial liquid handling, Sanofi requests healthcare professionals to prepare the solutions with the utmost care and attention.

Call for reporting

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Fasturtec according to national reporting requirements. Please report suspected adverse events to the Medicines Authority; ADR report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and sent to postlicensing.medicinesauthority@gov.mt or sent to ADR reporting 201, level 3, Rue d'Argens Gzira/GZR 1368 or to the Marketing Authorisation Holder, Sanofi, via the following email address: pharmacovigilancemalta@sanofi.com

Company contact point

e-mail (Italy&Malta): Informazioni.medicoscientifiche@sanofi.com
Phone (Malta): +39 02 39394275