<Date>

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 <INSERT COUNTRY> (or Sanofi Winthrop Industrie) in agreement with the European Medicines Agency and <National Competent Authority where applicable; if this DHPC has been validated by local authority> would like to inform you of the following important information about rasburicase.

Summary

- **In <INSERT COUNTRY>, supply of Fasturtec® (rasburicase) 7.5 mg/5 ml presentation is expected to be constrained from March 31st, 2023 until <INSERT DATE AND MONTH AS PER INDIVIDUAL COUNTRY>. [Each country to adapt according to specific supply situation]**

- **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 national level according to the local approved labelling 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.

Ca*ll for reporting*

Healthcare professionals should report adverse reactions <and medication error IF APPLICABLE> in accordance with the national spontaneous reporting system <INSERT CONTACT DETAILS (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

Company contact point

Should you have any questions or require additional information, please call Medical Information at <INSERT CONTACT DETAILS OF SANOFI LOCAL REPRESENTATIVE IN MEMBER STATE>.

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

Direct Healthcare Professional Communication Plan

DHPC COMMUNICATION PLAN	
Medicinal product/active substance	**Fasturtec** 1.5 mg/ml powder and solvent for concentrate for solution for infusion Active substance: rasburicase Content: **7.5 mg/5 ml** pack size: **1 vial + 1 ampoule of solvent** MA (EU) Number: **EU/1/00/170/002**
Marketing authorisation holder	Sanofi Winthrop Industrie 82 avenue Raspail 94250 Gentilly France
Safety concern and purpose of the communication	To inform relevant HCPs in affected countries of supply shortage of Fasturtec® 7.5 mg/5 ml powder and solvent for concentrate for solution for infusion (EU/1/00/170/002)
DHPC recipients	should be further defined on national level, depending on national health care systems.
Member States where the DHPC will be distributed	In all EEA countries where Fasturtec® 7.5 mg/5 ml powder and solvent for concentrate for solution for infusion (EU/1/00/170/002) is on the market

Timetable (Delete steps that are not applicable)	Date
DHPC and communication plan (in English) agreed by CHMP/CMDh	26/01/2023
Submission of translated DHPCs to the national competent authorities for review	Within 10 days after receipt of the approved DHPC
Agreement of translations by national competent authorities	According to the timelines set by NCAs (generally within 5 working days)
Dissemination of DHPC	Within 2 weeks after respective NCA approval By 20 Feb 2023