Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 24 August 2020 EL (20)A/40 Our Ref: MDR 091-08/20

Dear Healthcare Professional,

Sanofi

Fasturtec® 7.5 mg. 1.5 mg/ml powder and solvent for concentrate for solution for infusion EU/1/00/170/002

Batch Number	Expiry Date	Pack Size	First Distributed
A9306	02 / 2022	7.5mg vial	14/11/2019

Generic Name: rasburicase

Brief description of problem

Sanofi has informed us of an Out Of Specification (OOS) result which was detected for Rasburicase enzyme activity according to a specific method and specifications for US market, at 12 months stability time point. Sanofi is recalling Fasturtec® 7.5 mg (Rasburicase) Solution for IV infusion - 7.5 mg/5 ml (Injectable powder in vial packaged with 5 ml solvent in ampoule), batch number A9306 as a precautionary measure.

Advice for healthcare professionals

Stop supplying the above batch immediately. Quarantine all remaining batch stock and return it to your supplier using your supplier's approved process.

Company contacts for further information

For medical information enquiries please contact uk-medicalinformation@sanofi.com Med Info Phone : 0800 035 25 25. For stock control enquiries please contact GB-CustomerServices@sanofi.com Phone number: 0800 854 430

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this alert to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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