



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level

Date: 26 November 2020

EL (20)A/56

Our Ref: MDR 140-11/20

Dear Healthcare Professional,

Aventis Pharma Limited (t/a Sanofi)

Largactil 50mg/2ml Solution for Injection

PL 04425/0582

Batch Number	Expiry Date	Pack Size	First Distributed
A90142	05/2022	10 x 2ml ampoules	08 April 2020
A90143	05/2022	10 x 2ml ampoules	10 June 2020

Active Pharmaceutical Ingredient: chlorpromazine hydrochloride

Brief description of the problem

Sanofi is recalling the above batches due to out of specification results obtained for the impurity chlorpromazine sulphoxide, which was suspected to be caused by increased oxidation as a result of higher oxygen content in the headspace of the ampoules. As a precautionary measure, the above batches are being recalled.

Advice for healthcare professionals

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

Further Information

For stock control enquiries please contact GB-CustomerServices@sanofi.com
Phone number: 0800 854 430

For more information or medical information at uk-medicalinformation@sanofi.com
Phone number: 0800 035 25 25

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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