

Drug Alert

CLASS 2 MEDICINES DEFECT INFORMATION

Class II Recall Notification up to Pharmacy and Wholesaler Level Action within 48 hours

Date: 27th November 2020

Our Ref: MDR xx/20

Dear Healthcare Professional,

For the attention of the Responsible Person/Managing Pharmacist

Brand Name: **Chlorpromazine hydrochloride 25mg/ml x 2ml (Largactil ®) – Sanofi**
PL04425/0582

Sage No.	Dose	Batch No.	Expiry Date
J052	Chlorpromazine hydrochloride 25mg/ml x 2ml (Largactil ®)	A90142	May 2022
J052	Chlorpromazine hydrochloride 25mg/ml x 2ml (Largactil ®)	A90143	May 2022

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.

In Malta, this recall is being carried out **up to Pharmacy and Wholesaler Level** by CPSU under the supervision of the Medicines Authority. Distribution has been done solely by CPSU.

You are kindly requested to liaise with David Baldacchino on +356 25404113 email david.baldacchino@gov.mt or Ms Bernardette Brincat, Principal Pharmacy Technician (For emergencies, kindly contact on mobile: 79538319) and/, CPSU San Gwann Stores, to return remaining stock of the above batch to CPSU San Gwann Stores by Monday, 30th November 2020. Stock should be clearly marked – ‘Recalled Stock and name of entity’.

Quantity and batch no. should be listed clearly on each cardboard box returned. Please forward details of specific quantities to the undersigned. Nil stocks are also to be communicated.

Sir Temi Zammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, MALTA
info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

Yours faithfully

Christopher Attard
Senior Medicines Authority

Medicines Authority Distribution (if applicable): None