



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 06 October 2022

EL (22)A/41

Our Ref: MDR 006-09/22

Dear Healthcare Professional,

Aventis Pharma Limited (t/a Sanofi)

Stemetil 5mg/5ml Syrup

PL 04425/0595

Batch Number	Expiry Date	Pack Size	First Distributed
0032	Feb 2023	100ml	17 Sep 2020
0033	Aug 2023	100ml	26 May 2021
0034	Sep 2024	100ml	14 Dec 2021
0035	Feb 2025	100ml	04 May 2022

Active Pharmaceutical Ingredient: Prochlorperazine mesilate

Brief description of the problem

Sanofi is recalling all batches of the above product as a precautionary measure due to the identification of N-nitrosomethylphenylamine (NMPA) above the acceptable limit. Nitrosamines may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time.

Advice for healthcare professionals

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

Healthcare professionals should advise patients undergoing treatment not to discontinue Stemetil Syrup without consulting with their prescriber. If this medicine was abruptly withdrawn, there is a possibility of the return of symptoms for which Stemetil Syrup was prescribed, and more rarely, withdrawal reactions such as nausea, vomiting, insomnia and movement disorders.

Based on the available data, there is no immediate risk to patients who have been taking this medication. Patients should be advised to discuss any questions or concerns with their prescribing healthcare professional.

Advice for patients

- Stemetil Syrup should not be stopped without talking to your prescriber. Based on current evidence, there is no immediate risk to patients who have been taking this medication.
- However, the Marketing Authorisation Holder will be stopping further supply of Stemetil Syrup following laboratory test results demonstrating excess levels of a chemical impurity that may potentially increase the risk of cancers if taken for a long time.
- Your prescriber should review your treatment and consider switching to a suitable alternative going forward.

Further Information

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



Medicines & Healthcare products Regulatory Agency

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

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

Yours faithfully

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