Direct Healthcare Professional Communication

10th November 2022

Stemetil (Prochlorperazine mesilate) 5 mg / 5 ml Syrup: permanent discontinuation due to laboratory test results demonstrating excess levels of N-nitrosomethylphenylamine

Dear Healthcare Professional

Sanofi, in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- Stemetil 5 mg / 5 ml Syrup is being permanently discontinued in the UK from October 2022.
- All healthcare professionals in primary, secondary and specialist healthcare services should:
  - not initiate Stemetil Syrup in new patients
  - identify patients currently prescribed Stemetil Syrup and arrange for a review of treatment
  - review treatment and, following discussion with the patient being treated, switch to an alternative treatment
- Healthcare professionals should advise patients undergoing treatment not to discontinue Stemetil Syrup without consulting their prescriber. If this medicine was withdrawn abruptly, there is a possibility of the return of symptoms for which Stemetil Syrup was prescribed, and more rarely, withdrawal reactions, such as nausea,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 involuntary movement disorders.

Background

Product Name: Stemetil 5 mg / 5 ml Syrup
INN: Prochlorperazine Mesilate
Marketing Authorisation Holder: Aventis Pharma Ltd, trading as Sanofi
Shelf life: 3 Years

Stemetil is indicated for Vertigo due to Meniere's Syndrome, labyrinthis and other causes, and for nausea and vomiting from whatever cause, including that associated with migraine. It may also be used for schizophrenia (particularly in the chronic stage), acute mania and as an adjunct to the short-term management of anxiety.

Sanofi is the sole supplier of Stemetil Syrup (Prochlorperazine mesilate), which is being discontinued from October 2022. This followslaboratory test results which demonstrated excess levels of the chemical impurity N-nitrosomethylphenylamine (NMPA), a nitrosamine compound.

The term “nitrosamine” describes a class of compounds having the chemical structure of a nitroso group bonded to an amine (R1N(-R2)-N=O). The compounds can be formed by a nitrosating reaction between amines (secondary, tertiary, or quaternary amines) and nitrous acid (nitrite salts under acidic conditions). Nitrosamines are a known environmental contaminant found in both industrial and natural processes, as well as water and foods (including meats, dairy products and vegetables).

Nitrosamines, like NMPA, are chemical compounds classified as probable human carcinogens on the basis of animal studies. If taken for a long time, they may potentially increase the risk of cancers. Therefore, the benefit risk of Stemetil Syrup is considered unfavourable.

Please refer to the MHRA Class 2 Recall Notification for Stemetil Syrup for more information.

The other pharmaceutical forms of Stemetil (tablet or injectable) are not affected by this nitrosamine risk and remain available.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website – https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

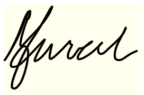
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse events arising from the use of medicines manufactured by Sanofi may also be reported to:
Sanofi Pharmacovigilance, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK
Tel: 0800 090 2314
Email: uk-drugsafety@sanofi.com

Company contact point

Should you have any questions or require additional information, please contact:
Sanofi Medical Information, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK
Tel: 0800 035 2525
Email: uk-medicalinformation@sanofi.com

Yours faithfully,



Deborah Woods
UK and Ireland, Head of General Medicines