Australian Government
Department of Health
Therapeutic Goods Administration

Stemetil 5 mg tablets

Recall – potential for missing blister sheet

1 June 2017

Consumers and health professionals are advised that Sanofi-Aventis Australia, in consultation with the TGA, is recalling one batch of Stemetil (prochlorperazine maleate) 5 mg tablets (batch number 16N0060, expiry date 06/2018).

It has been identified that this medicine may have been dispensed with a missing blister sheet, which means affected packs would not contain the correct number of tablets.

Stemetil is used to treat nausea, vomiting and dizziness due to various causes, including migraine (severe headache).

There are no issues with the quality, safety or efficacy of Stemetil tablets from the batch involved and no other batches are included in this recall.

Information for consumers

If you or someone you provide care for takes Stemetil, please check the batch number (displayed on the packs and blister sheet) to see if it is affected by this recall.

If you have a pack that has been affected by this issue, return any unused medicine to a pharmacy for a refund.

In the event that there are no anomalies with your product, you can choose to continue using it as normal.

If you notice any other anomaly with the product, or if you have any other questions or concerns about this issue, talk to your health professional or contact Sanofi-Aventis Medical Information on 1800 818 806. If you have any questions regarding returning stock or affected batch details call the Sanofi Product Recall Team on 1800 152 416 (9am-5pm Eastern Time).

Information for health professionals

If you treat patients who take Stemetil, please be aware of this issue.

Sanofi-Aventis Australia has written to pharmacists providing further information about this issue, including details of the recall process.

Pharmacists should inspect their stock and quarantine all affected packs before returning them to their wholesaler.

In the event that there are no anomalies with your product, you can choose to continue using it as normal.

Pharmacists are advised that given the contents are a single blister strip of 25 tablets, the most likely scenario of a missing blister is an empty box, which should be easily detectable.

Patients returning unused or partially used packs of Stemetil should be provided a full refund. If the patient has a valid prescription (or repeat prescription) or if they meet Schedule 3 supply requirements as per the Poisons Standards, they should be offered an equivalent product to ensure continuation of therapy.

If you have any further questions or concerns about this issue, please contact Sanofi-Aventis Australia Medical Information on 1800 818 806. If you have any questions regarding returning stock or affected batch details call the Sanofi Product Recall Team on 1800 152 416 (9am-5pm Eastern Time).

Reporting problems

Consumers and health professionals are encouraged to report problems with medicines or vaccines (/reporting-problems). Your report will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medicine or vaccine.

Category: Alert/Advisory, Medicines safety
Tags: recalls

URL: https://www.tga.gov.au/node/756509 (//www.tga.gov.au/alert/stemetil-5-mg-tablets)

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