COMMUNICATION

2022-054

5 OCTOBER 2022

PLEASE Recall Notification

REVIEW PharmPix Clinical Department



09/29/2022

Drug Information:

National Drug Code

CLOPIDOGREL 75 MG TABLETS:

51407-032-10

ATENOLOL 25 MG TABLETS:

60429-027-10

Product Description

CLOPIDOGREL 75 MG TABLETS 1000 COUNT BOTTLE

ATENOLOL 25 MG TABLETS 1000 COUNT BOTTLE

Batch Number

GS046745

Expiration Date

DECEMBER 2023

Company:

GOLDEN STATE MEDICAL SUPPLY, INCORPORATED (GSMS, INC.)

QUESTIONS

GSMS, INC.

(800)284-8633, EXT 116

7:30 AM - 4:00 PM, PDT



PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

CLOPIDOGREL 75 TABLETS & ATENOLOL 25 MG TABLETS

It is for this reason that we are notifying you that on 09.29.2022 the US Food and Drug Administration (FDA) published a drug recall for the following products: Clopidogrel 75mg Tablets and Atenolol 25mg Tablets

Pharmacy Required Action:

Identify if the product is in inventory, immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

A voluntary recall of the products mentioned previously was made because a report was received that a bottle containing Clopidogrel 75mg Tablets was mislabeled as Atenolol 25mg Tablets. This voluntary recall only affects products with lot #GS046745.

If clopidogrel was misplaced in an atenolollabeled bottle, patients who suddenly stopped taking atenolol could be at increased risk for ischemic (angina, myocardial infarction), hypertensive and arrhythmic adverse events relating to rapid withdrawal of beta antagonism.

Also, patients who are on atenolol are frequently on concomitant anticoagulant and antiplatelet medications. Hence, they would be at increased risk for bleeding if clopidogrel was added to the regimen.

To date, GSMS, Inc. has not received any reports of adverse events related to the use of the products as part of this recall.



Remember you can report adverse events related to this or any other drug product at <u>MedWatch</u>: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

<u>Download</u> FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252 - Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number 054 October 2022





REFERENCES

- U.S. Food and Drug Administration. (2022). Golden State Medical Supply, Inc. Issues a Voluntary Nationwide Recall of Atenolol 25 mg Tablets and Clopidogrel 75 mg Tablets Due to a Label Mix-up. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/golden-state-medical-supply-inc-issues-voluntary-nationwide-recall-atenolol-25-mg-tablets-and.
 MedWatch: The FDA Safety Information and Adverse Event Reporting Program https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-
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