Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-077-CG
October 3, 2022

FDA announced that, **Golden State Medical Supply, Incorporated (GSMS, Inc.) - Camarillo, CA** has initiated a voluntary recall of the products listed in the table below because a report was received that a bottle containing Clopidogrel 75mg Tablets produced with lot# GS046745 was mislabeled as Atenolol 25mg Tablets. This voluntary recall only affects products with lot# GS046745. No other Clopidogrel or Atenolol products marketed by GSMS, Inc. are impacted. Both products are being recalled out of abundance of caution.

RECOMMENDATIONS

1. AmerisourceBergen and McKesson are instructed to immediately stop distribution, quarantine all remaining products in their control, and return the recalled product to GSMS, Inc.

2. Consumers with questions regarding this recall can contact GSMS, Inc, by: Phone: (800) 284-8633, ext. 116 (include days between 7:30 AM to 4:00 PM, Pacific)

3. Review your inventory to identify existence of recalled products.

4. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
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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

Summary:

Company Announcement Date:	September 29, 2022
FDA Publish Date:	September 29, 2022
Product Type:	Drugs
Reason for Announcement:	Due to Label Mix-up
Company Name:	Golden State Medical Supply, Incorporated
Brand Name:	Golden State Medical Supply, Incorporated
Product Description:	Clopidogrel 75mg Tablets, Atenolol 25mg Tablets

Company Announcement

FOR IMMEDIATE RELEASE- SEPTEMBER 29, 2022, Golden State Medical Supply, Incorporated (GSMS, Inc.) - Camarillo, CA has initiated a voluntary recall of the products listed in the table below because a report was received that a bottle containing Clopidogrel 75mg Tablets produced with lot# GS046745 was mislabeled as Atenolol 25mg Tablets. This voluntary recall only affects products with lot# GS046745. No other Clopidogrel or Atenolol products marketed by GSMS, Inc. are impacted. Both products are being recalled out of abundance of caution.

Product Description	GSMS NDC	Lot #	Expiration Date
Clopidogrel 75mg Tablets, 1,000 Count Bottle	51407-032-10	GS046745	12/2023
Atenolol 25mg Tablets, 1,000 Count Bottle	60429-027-10	GS046745	12/2023

Atenolol tablets are indicated for the treatment of hypertension, to lower blood pressure. Clopidogrel is prescribed to lower the risk of having a stroke, blood clot, or serious heart problem for patients who have had heart attack, severe chest pain, or circulation problems as indicated in the product labeling. For more drug label information about clopidogrel bisulfate visit: DailyMed - CLOPIDOGREL- clopidogrel bisulfate tablet, film coated (nih.gov). For more drug label information about atenolol visit: DailyMed - ATENOLOL tablet (nih.gov).

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Patients who suddenly stop taking atenolol, as would happen if clopidogrel were misplaced in the atenolol-labeled bottle, are at increased risk for ischemic (angina, myocardial infarction), hypertensive and arrhythmic adverse events relating to rapid withdrawal of beta antagonism. Further, patients who are on atenolol are frequently on concomitant anticoagulant and antiplatelet medications and would be at increased risk for bleeding if clopidogrel were 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.

The lot under GSMS, Inc.'s voluntary recall has been primarily sold to AmerisourceBergen, and McKesson. AmerisourceBergen and McKesson are instructed to immediately stop distribution, quarantine all remaining products in their control, and return the recalled product to GSMS, Inc. They are also instructed to provide their customers, i.e., pharmacies and consumers, a copy of GSMS, Inc.'s recall notification, recall response form, and letter to consumers, patients, and caregivers.

Consumers with questions regarding this recall can contact GSMS, Inc, by: Phone: (800) 284-8633, ext. 116 (include days between 7:30 AM to 4:00 PM, Pacific).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

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