

June 2020

<Ship_first_nme> <Ship_last_nme>
<patient_address_1>
<patient_address_2>
<patient_city>, <patient_state> <patient_zip>

Here's important news about your medication. Action is required.

Dear << PATIENT FIRST NME> <PATIENT LAST NME>>:

As your home delivery pharmacy, we care about your health and want to ensure you are aware of a recent recall for <<LABEL TEXT >>. This voluntary drug product recall includes Metformin Extended Release (ER) batches that have been sourced by the Department of Defense (DoD) from AvKARE. The recall is due to the presence of N-Nitrosodimethylamine (NDMA), a substance that is commonly ingested in water or food, but prolonged exposure at above-acceptable levels could cause cancer. Certain batches of Metformin Hydrochloride **Extended Release** Tablets, USP, 500mg and 750mg, showed N-Nitrosodimethylamine (NDMA) amounts above acceptable FDA levels.

To date, no reports of adverse events related to this drug product recall have been reported. Our records show that <PATIENT_FIRST_NME> <PATIENT_LAST_NME> recently filled a prescription for the recalled drug product within the past 120 days. Below is some detail about that order.

NDC>>

What You Need to Know

Metformin Hydrochloride Extended-Release Tablets, USP is a prescription oral drug product indicated as an adjunct to diet and exercise to improve blood sugar control in adults and pediatric patients, 10 years of age and older, with type 2 diabetes mellitus. **Therefore, it is important you do not stop taking your medication without consulting your prescriber.** If you have health concerns, contact your prescriber.

Future refills: Be assured your next refill will be from drug product that is not affected by this recall.

- If it is time for your next refill, you can call the toll-free number on your bottle or request your refill through https://militaryrx.express-scripts.com.
- To replace your current prescription with a new supply now, please call the toll-free number on your prescription bottle.
- If you have concerns with taking this medication, please contact your prescriber to discuss other options such as immediate release metformin.
- If you and your provider decide to change to a different medication, please submit a new prescription electronically or by mail.

About the drug product recall:

For more information about this drug product recall, or to report adverse events or quality problems experienced with the use of this drug product, visit https://militaryrx.express-scripts.com/notices/recall

You can report adverse events or quality problems related to the use of the drug product to the FDA's MedWatch Adverse Events Reporting Program. Call 800.FDA.1088 or go to fda.gov/Safety/MedWatch/ HowToReport/default.htm.

Sincerely, Your Home Delivery Pharmacy

Please turn the page for frequently asked questions

Frequently Asked Questions

- 1. I have been taking the medication for months. Why are you just now notifying me?

 As soon as we receive a drug product recall notice, we determine who may be impacted and communicate at that time.
- 2. How do I know that the medication I get in the future is safe to take?

 We care about your health and are working to supply you with drug product from manufacturers that meet the FDA guidelines for impurity levels of this medication. If you have any medical concerns using what you receive in the future, please contact your prescriber and talk about your therapy options.
- 3. Can you just send me a replacement?

 Express Scripts Pharmacy® will be able to assist with providing a refill or replacement of unaffected medication or filling a new prescription (if your prescriber has decided to change therapy) to ensure you have medication on hand. Guidelines for appropriate disposal of medications can be found at: https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines