Jul 21, 2021

Expiration date extension: February 2022 to February 2023 for LANOXIN® (digoxin) tablets; Strength: 62.5 mcg (0.0625 mg); Lot# AL0071A; NDC# 59212-240-55 (bottle of 100s).

Dear Healthcare Professional,

To avoid a drug shortage **Concordia Pharmaceuticals Inc**. ("Concordia") would like to inform you that the expiry date of **Lanoxin strength 62.5 mcg (0.0625 mg) (Lot#AL0071A**), has been extended from **February 2022 to February 2023**.

Concordia is anticipating some manufacturing issues, because of which, release of a new batch of product in the market might get delayed. Concordia is coordinating with the U.S. Food and Drug Administration (FDA)to extend the expiration date of Lanoxin strength 62.5 mcg (0.0625 mg) (Lot# AL0071A), from February 2022 to February 2023, to ensure a continued supply of this drug until Concordia resolves the manufacturing issues.

Concordia is the sole supplier of the product LANOXIN® (digoxin) 62.5 mcg (0.0625 mg) in the USA, indicated for the treatment of:

- mild to moderate heart failure in adults,
- increasing myocardial contractility in pediatric patients with heart failure and
- control of resting ventricular rate in patients with chronic atrial fibrillation in adults.

The stability profile of LANOXIN® (digoxin) 62.5 mcg (0.0625 mg) has been reviewed and this extension of the expiry date by one year does not impact the quality, safety, or efficacy of this product.

We appreciate your patience and cooperation. For any questions related to this product, or to report suspected adverse reactions experienced with the use of this product and/or quality problems, please contact your account manager or Concordia Pharmaceuticals Inc. Customer Service at: **1-877-370-1142**

Adverse events or quality problems experienced with the use of this product may also 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 (1-800-332-0178).

This letter is not intended to be a complete description of the benefits and risks related to the use of Lanoxin Please refer to the enclosed full prescribing information.

Sincerely,
Concordia Pharmaceuticals Inc.