Marlex – Recall of digoxin tablets

- On August 30, 2023, Marlex announced a consumer level recall of one lot of digoxin 0.125 mg and one lot of digoxin 0.25 mg tablets because of a label mix-up. Bottles of digoxin 0.125 mg are incorrectly labeled and contain digoxin 0.25 mg tablets. Bottles of digoxin 0.25 mg tablets are incorrectly labeled and contain digoxin 0.125 mg tablets.
    - Clinical Services identified potentially impacted members and will send notifications to the members and their prescribers.
    - The member letter advises members to contact their pharmacy for a replacement.

Product Description	NDC Number	Lot Number (Exp Date)
Digoxin 0.125 mg tablet	10135-0747-01	E3810 (2/2025)
Digoxin 0.25 mg tablet	10135-0748-01	E3811 (2/2025)

- Digoxin is indicated for the treatment of heart failure in adults and pediatric patients, and for atrial fibrillation in adults.
- The mix-up in labels can cause either overdosing or underdosing in patients who unknowingly take the wrong dose. Patients who intend to take digoxin 0.125 mg, but unknowingly digoxin 0.25 mg would receive a super potent dose and can experience significant drug toxicity (mental disorientation, dizziness, blurred vision, memory loss and fainting) from the unintentional overdose.
- Patients who intend to take digoxin 0.25 mg, but unknowingly take digoxin 0.125 mg would receive a sub potent dose which may lead to loss of control of heart rate and potential heart failure exacerbation.
- Marlex has not received any reports of adverse events related to this recall.
- Anyone with the affected lot on hand should stop use and distribution and return to place of purchase.
- Contact Marlex at **1-302-328-3355** or **1-888-582-1953** for questions regarding this recall.