**PANTOPRAZOLE SODIUM DELAYED RELEASE- pantoprazole sodium delayed release tablet, delayed release**
**Northwind Pharmaceuticals**

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NDC: 51655-500-52

MFG: 0378-6689-10

Pantoprazole Sodium Delayed Release 40 MG

30 Tablets

Rx only

Lot#:

Exp. Date:

Each film-coated tabler contains: pantoprazole sodium, USP equivalent to 40 mg of pantoprazole

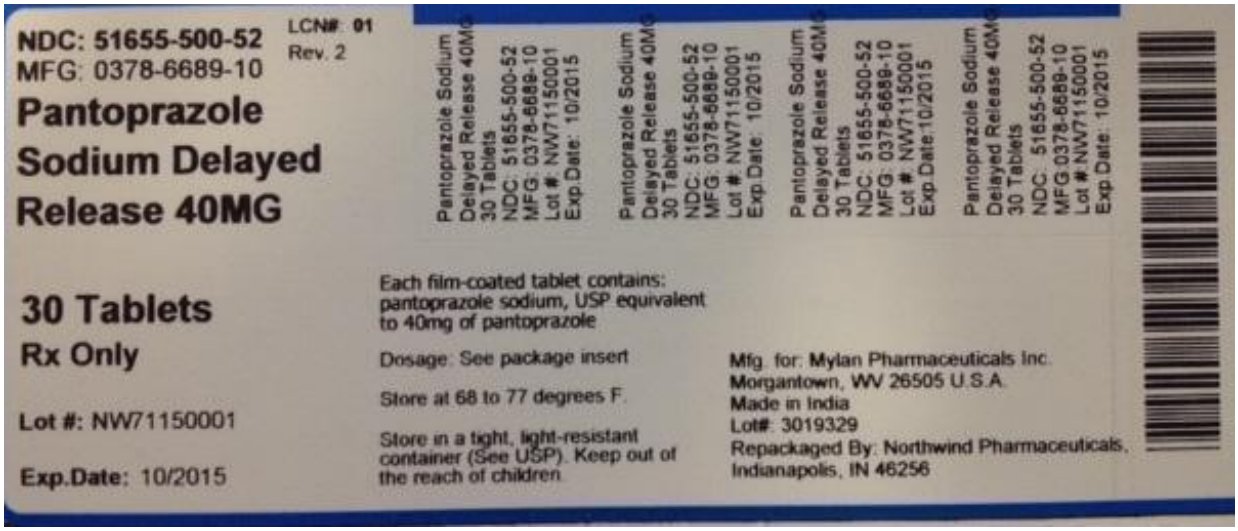
Dosage: See package insert

Store at 66-77 degrees F.

Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Mfg for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 USA Made in India Lot#:

Repackaged by: Northwind Pharmaceuticals, Indianapolis, IN 46256




## Indications and Usage

Pantoprazole is a proton pump inhibitor indicated for the following:

•Short-term Treatment of Erosive Esophagitis Associated with Gastroesophageal Reflux Disease (GERD).

•Maintenance of Healing of Erosive Esophagitis.

•Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome.

## Warnings and Precautions

•Symptomatic response does not preclude presence of gastric malignancy.

•Atrophic gastritis has been noted with long-term therapy.

•PPI therapy may be associated with increased risk of Clostridium difficile associated diarrhea.

•Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine.

•Hypomagnesemia has been reported rarely with prolonged treatment with PPIs

### Adverse Reactions

The most frequently occurring adverse reactions are as follows:

•For adult use (> 2%) are headache, diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, and arthralgia.

**To report SUSPECTED ADVERSE REACTIONS, contact Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**

### Drug Interactions

•Do not coadminister with atazanavir or nelfinavir.

•Concomitant warfarin use may require monitoring.

•May interfere with the absorption of drugs where gastric pH is important for bioavailability.

•May produce false-positive urine screen for THC.

•Methotrexate: Pantoprazole may increase serum level of methotrexate

Information describing use in pediatric patients with erosive esophagitis associated with GERD is approved for Wyeth Pharmaceuticals Inc.'s pantoprazole sodium delayed-release tablets. However, due to Wyeth Pharmaceuticals Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

## PANTOPRAZOLE SODIUM DELAYED RELEASE

pantoprazole sodium delayed release tablet, delayed release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:51655-500(NDC:0378-6689) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **PANTOPRAZOLE SODIUM** (UNII: 6871619Q5X) (PANTOPRAZOLE - UNII:D8TST4O562) | PANTOPRAZOLE | 40 mg |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | OVAL | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | M;P9 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:51655-500-52 | 30 in 1 BOTTLE, DISPENSING | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA090970 | 03/21/2014 | |

## Labeler - Northwind Pharmaceuticals (036986393)

## Registrant - Northwind Pharmaceuticals (036986393)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Northwind Pharmaceuticals | | 036986393 | repack(51655-500) |

Revised: 6/2014 Northwind Pharmaceuticals