**LANSOPRAZOLE- lansoprazole capsule, delayed release**
**Rugby Laboratories, Inc.**

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**DRUG FACTS**

**Active ingredient (in each capsule)**

Lansoprazole USP, 15 mg

**Purpose**

Acid reducer

**Use**

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**WARNINGS**

**Allergy alert:** Do not use if you are allergic to lansoprazole.

**Do not use**

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

**Ask a doctor before use if you have**

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

**Ask a doctor or pharmacist before use if you are**

taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus or mycophenolate mofetil (immune system medicine)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

**Repeated 14-Day Courses (if needed)**

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

**Other information**

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20°-25°C (68°-77°F)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

**Inactive ingredients**

black iron oxide,colloidal silicon dioxide, corn starch, FD&C Blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, sugar spheres (corn starch and sucrose), talc, titanium dioxide, yellow iron oxide

**Questions or comments?**

Call **1-800-645-2158**

**Principal Display Panel**

Compare to the active ingredient in Prevacid® 24HR†

Lansoprazole Delayed-Release

Capsules USP, 15 mg

Acid Reducer

**Treats Frequent Heartburn**

- May take 1 to 4 days for full effect
- Sodium free

Capsules

Three 14-day Course of Treatment

†This product is not manufactured or distributed by Takeda Pharmaceuticals North America, Inc., owner of the registered trademark Prevacid®, or by GSK Consumer Healthcare, distributor of the Prevacid® 24HR product.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP OR BLACK BAND AROUND THE CENTER OF EACH CAPSULES IS BROKEN OR MISSING.**

**KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION**

**Distributed by:**

**Rugby Laboratories**

17177 N Laurel Park Drive, Suite 233

Livonia, MI48152

www.rugbylaboratories.com

**Package Label**


**RUGBY Lansoprazole Delayed-Release Capsules**

| **LANSOPRAZOLE**<br>lansoprazole capsule, delayed release |
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## Product Information

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|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0536-1236 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **LANSOPRAZOLE** (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG) | LANSOPRAZOLE | 15 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 3** (UNII: PN2ZH5LOQY) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYDROXYPROPYL CELLULOSE, UNSPECIFIED** (UNII: 9XZ8H6N6OH) | |
| **HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED** (UNII: 2165RE0K14) | |
| **MAGNESIUM CARBONATE** (UNII: 0E53J927NA) | |
| **METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A** (UNII: NX76LV5T8J) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **AMMONIA** (UNII: 5138Q19F1X) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | PINK, GREEN | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 18mm |
| **Flavor** | | **Imprint Code** | MYL;LD15 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0536-1236-13 | 3 in 1 BOX | 05/31/2019 | |
| **1** | | 14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:0536-1236-88 | 1 in 1 BOX | 05/31/2019 | |

| | | | | |
|---|---|---|---|---|
| **2** | | 14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA203187 | 05/31/2019 | |

## Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 7/2019 Rugby Laboratories, Inc.