**LORATADINE AND PSEUDOEPHEDRINE - loratadine and pseudoephedrine tablet, extended release**
**Physicians Total Care, Inc.**

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**DRUG FACTS**

**ACTIVE INGREDIENTS (IN EACH TABLET)**

Loratadine, USP 10 mg

Pseudoephedrine sulfate, USP 240 mg

**PURPOSE**

Antihistamine

Nasal decongestant

**USES**

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - sneezing
  - itchy, watery eyes
  - runny nose
  - itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

**WARNINGS**

**Do not use**

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

**When using this product do not take more than directed.**

Taking more than directed may cause drowsiness.

**Stop use and ask a doctor if**

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever.
- nervousness, dizziness or sleeplessness occurs

**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 right away (1-800-222-1222).

**DIRECTIONS**

- do not divide, crush, chew or dissolve the tablet
- adults and children 12 years and over: 1 tablet daily with a full glass of water; not more than 1 tablet in 24 hours
- children under 12 years of age: ask a doctor
- consumers with liver or kidney disease: ask a doctor

**OTHER INFORMATION**

- **sodium**: contains 10 mg/tablet
- **calcium**: contains 25 mg/tablet
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.** ***(for blister carton/label*****)**
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.** ***(for bottle carton/label)***
- store between 20° C to 25° C (68° F to 77° F)
- protect from light and store in a dry place

**INACTIVE INGREDIENTS**

calcium carbonate, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

**QUESTIONS?**

call **1-800-406-7984**

**PACKAGE LABEL. PRINCIPAL DISPLAY PANEL**

**NDC 54868-5656-2**

**Original Prescription Strength**

**Non-Drowsy***

**Loratadine and Pseudoephedrine Sulfate Extended-Release Tablets**

**(24 hour Formulation)**

**Loratadine, USP 10 mg/Antihistamine**

**Pseudoephedrine Sulfate, USP 240 mg/Nasal Decongestant**

**Indoor & Outdoor Allergies**

**Relief of:**

**Nasal & Sinus Congestion Due to Colds or Allergies**

**Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose Due to Allergies**

**Allergy & Congestion**

***When taken as directed. See Drug Facts Panel.**

**Keep the carton. It contains important information.**

**See end panel for expiration date.**

Distributed by:

Ohm Laboratories Inc.

1385 Livingston Avenue

North Brunswick, NJ 08902

Additional bar code label applied by:

Physicians Total Care, Inc.

Tulsa, Oklahoma 74146

## LORATADINE AND PSEUDOEPHEDRINE

loratadine and pseudoephedrine tablet, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:54868-5656(NDC:51660-724) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **LORATADINE** (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) | LORATADINE | 10 mg |
| **PSEUDOEPHEDRINE SULFATE** (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE SULFATE | 240 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |

| | |
|---|---|
| **CALCIUM CARBONATE** (UNII: H0G9379FGK) | |
| **COLLOIDAL SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYDROXYPROPYL CELLULOSE** (UNII: RFW2ET671P) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **FERRIC OXIDE BLACK** (UNII: XM0M87F357) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL** (UNII: 3WJQ0SDW1A) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **STARCH, PREGELATINIZED CORN** (UNII: O8232NY3SJ) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM ALGINATE** (UNII: C269C4G2ZQ) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | RX724 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:54868-5656-0 | 30 in 1 BOTTLE | | |
| **2** | NDC:54868-5656-1 | 2 in 1 CARTON | | |
| **2** | | 5 in 1 BLISTER PACK | | |
| **3** | NDC:54868-5656-2 | 3 in 1 CARTON | | |
| **3** | | 5 in 1 BLISTER PACK | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA076557 | 05/27/2008 | |

## Labeler - Physicians Total Care, Inc. (194123980)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Physicians Total Care, Inc. | | 194123980 | relabel |