**ZEPHREX D- pseudoephedrine hydrochloride capsule, gelatin coated**
**L. Perrigo Company**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Zephrex D Drug Facts**

**Active ingredient (in each softgel)**

Pseudoephedrine HCl 30 mg

**Purpose**

Nasal decongestant

**Uses**

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

**Warnings**

**Do not use**

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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

**When using this product**

**do not exceed recommended dosage**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days or occur with a fever

**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**

| | |
|---|---|
| adults and children 12 years and over | • take 2 softgels every 4 to 6 hours<br>• do not take more than 8 softgels in 24 hours |
| children ages 6 to under 12 years | • take 1 softgel every 4 to 6 hours<br>• do not take more than 4 softgels in 24 hours |
| children under 6 years | do not use this product in children under 6 years of age |

**Other information**

- store at 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

**Inactive ingredients**

croscarmellose sodium, FD&C red no. 40, gelatin, guar gum, hydroxypropylcellulose, lecithin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, purified water, sorbitan, sorbitol, titanium dioxide, vegetable oil, xanthan gum

**Questions or comments?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

NEW DOSAGE FORM

MAXIMUM STRENGTH

ZEPHREX-D ®

CONGESTION

Pseudoephedrine HCl 30 mg

Nasal Decongestant

METH BLOCKING TAREX® TECHNOLOGY ™

Non-Drowsy

Relieves

Nasal & Sinus Congestion

Sinus Pressure

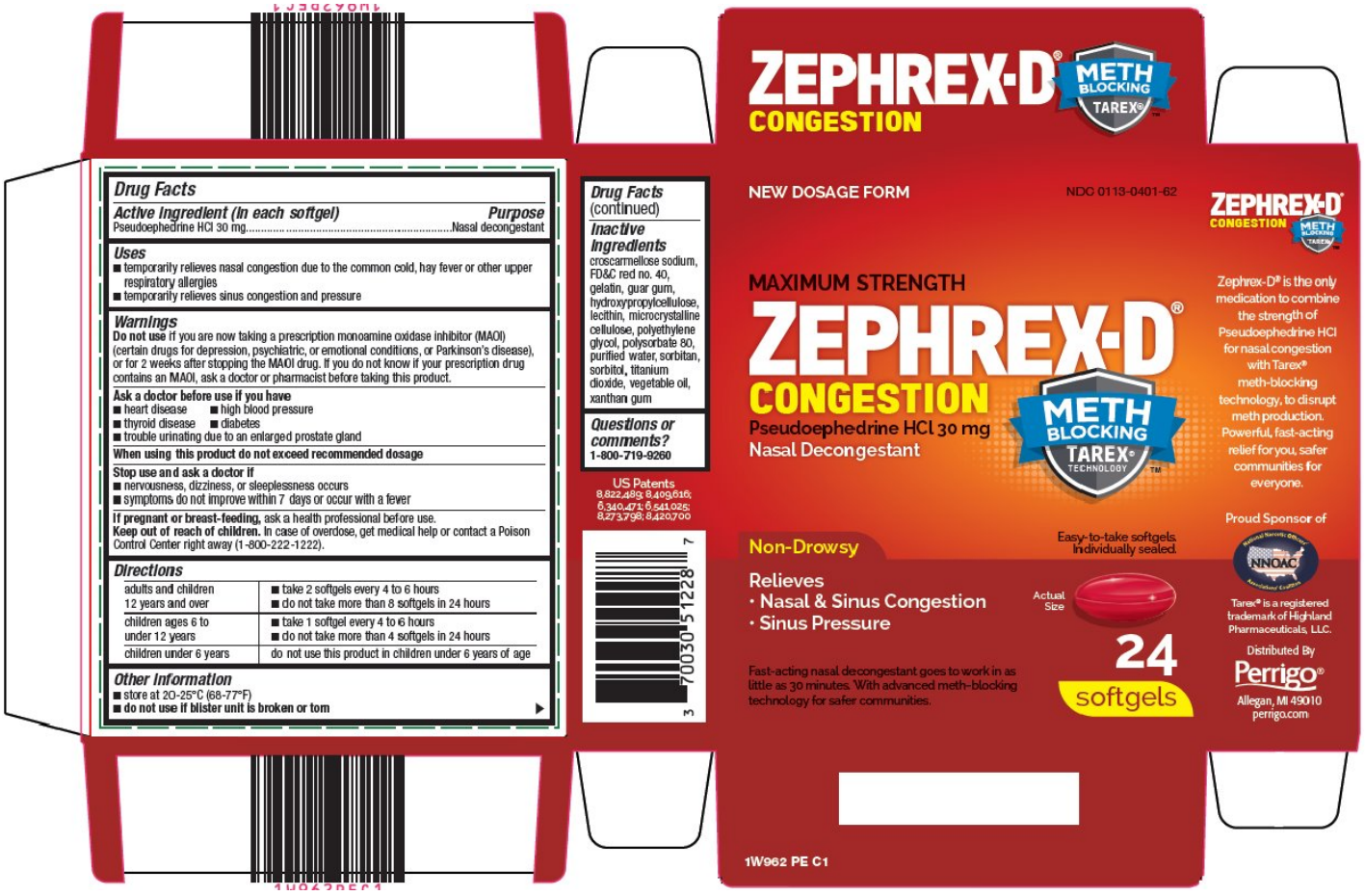
Easy-to-take softgels.

Individually sealed.

Actual Size

Fast-acting nasal decongestant goes to work in as little as 30 minutes. With advanced meth-blocking technology for safer communities.

24 softgels




# ZEPHREX D

pseudoephedrine hydrochloride capsule, gelatin coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0113-0401 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **PSEUDOEPHEDRINE HYDROCHLORIDE** (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 30 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GELATIN, UNSPECIFIED** (UNII: 2G86QN327L) | |
| **GUAR GUM** (UNII: E89I1637KE) | |
| **HYDROXYPROPYL CELLULOSE (1600000 WAMW)** (UNII: RFW2ET671P) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SORBITAN** (UNII: 6O92ICV9RU) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | RED | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | ZD3 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0113-0401-62 | 24 in 1 CARTON | 04/17/2017 | |
| **1** | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:0113-0401-67 | 48 in 1 CARTON | 05/08/2017 | |
| **2** | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 11/04/2016 | |

## Labeler - L. Perrigo Company (006013346)

Revised: 11/2020 L. Perrigo Company