

ZEPHREX-D- pseudoephedrine hydrochloride tablet
Westport Pharmaceuticals

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.

Active Ingredients (in each pill)

Pseudoephedrine HCl 30 mg

Purpose

Nasal Decongestant

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)

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 dose

Stop and ask a doctor if

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

If pregnant or breast-feeding, ask a health professional before use.

Directions: remove pill from sealed, plastic packaging before ingesting
swallow whole – do not crush, chew or dissolve

adults and children 12 years and over • take 2 pills every 4 to 6 hours

- do not take more than 8 pills in 24 hours

children ages 6 to under 12 years • take 1 pill every 4 to 6 hours

- do not take more than 4 pills in 24 hours

children ages under 6 years do not use this product in children

under 6 years of age

Inactive Ingredients croscarmellose sodium, guar gum, hydroxypropyl cellulose, lecithin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, vegetable oil, xanthan gum



ZEPHREX-D

pseudoephedrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53240-151
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
GUAR GUM (UNII: E89II637KE)	

HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53240-151-01	24 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/15/2012	

Labeler - Westport Pharmaceuticals (078368047)

Registrant - Elge Inc. (610655136)

Establishment

Name	Address	ID/FEI	Business Operations
Elge Inc.		610655136	manufacture(53240-151)

Revised: 5/2013

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