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

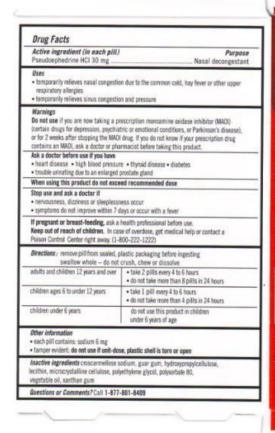
- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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 NDC:53240-151 Item Code (Source) Route of Administration ORAL

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demark of

Store at room

USE ONLY AS

DIRECTED

Westport

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Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg	

Inactive Ingredients		
Ingredient Name Streng		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
GUAR GUM (UNII: E8911637KE)		

HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDRO GENATED PALM KERNEL O IL (UNII: FM8 D1RE2VP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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

Pack	aging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	C: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	İ.		
Name	Address	ID/FEI	Business Operations
Elge Inc.		610655136	manufacture (53240-151)

Revised: 5/2013 Westport Pharmaceuticals