# 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.

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### 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 LABEL	Item Code (Source)	NDC:53240-151
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (PSEUDO EPHEDRINE)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg	

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
GUAR GUM	

HYDROXYPROPYL CELLULOSE	
LECITHIN, SO YBEAN	
CELLULO SE, MICRO CRYSTALLINE	
POLYETHYLENE GLYCOL 3350	
POLYSORBATE 80	
HYDRO GENATED PALM KERNEL O IL	
XANTHAN GUM	

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 Westport Pharmaceuticals