

**COLD MEDICINE XL3- acetaminophen chlorpheniramine maleate phenylephrine hydrochloride tablet**

**Selder, S.A. de C.V.**

*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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**Drug Facts**

**Active Ingredients (in each capsule)**

Acetaminophen 325 mg

Chlorpheniramine Maleate 4 mg

Phenylephrine Hydrochloride 10 mg

**Purpose**

Analgesic

Antihistamine

Decongestant

**Uses** temporarily relieves these symptoms due to common cold and allergies: • nasal congestion • runny nose • sneezing • watery eyes • fever • aches and pains

**Warnings**

**Do exceed recommended dosage**

Ask a doctor before use you have

- glaucoma • breathing problem such as emphysema or chronic bronchitis • heart disease • diabetes • thyroid disease
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

Stop taking this product and ask a doctor if you have • pain • fever or symptoms that persist or get worse

- new symptoms occur
- redness or swelling • these may be signs of a serious condition.

When using this product

- you may get drowsy • avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If nervousness, dizziness or sleeplessness occur discontinue use and consult a doctor

If symptoms do not improve within 7 days, or are accompanied by fever, consult a doctor

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

**Keep this and all drugs out of the reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

**Drug Interaction Precautions**

- Do not use if you are 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.

**Directions** Adults and children 12 years of age and older; take 1 tablet every 4 hours, do not take more than 6 tablets in 24 hours, unless directed by a doctor.

**Inactive Ingredients** Lactose, stearic acid, povidone, hydroxypropylmethylcellulose, polyethylene glycol, titanium dioxide, FDC Yellow No. 5

Package Label



## COLD MEDICINE XL3

acetaminophen chlorpheniramine maleate phenylephrine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63654-600
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### Product Characteristics

Color	yellow (light yellow)	Score	no score
Shape	ROUND (Tablet)	Size	5mm
Flavor		Imprint Code	XL;3
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-600-68	20 in 1 BLISTER PACK		
2	NDC:63654-600-02	25 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/15/2011	

**Labeler** - Selder, S.A. de C.V. (824413629)

### Establishment

Name	Address	ID/FEI	Business Operations
Selder, S.A. de C.V.		824413629	manufacture