

COLD MEDICINE- acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Selder, S.A. de C.V.

275 - XL-3 Cold Medicine

Active ingredients (in each tablet)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

Uses

temporarily relieves:

- minor aches and pains
- headaches
- nasal congestion
- sinus congestion & pressure
- runny nose
- sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening

- blisters

- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- if you are allergic to acetaminophen

- more than 10 days unless directed by a doctor

- 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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease

- heart disease

- glaucoma

- high blood pressure

- thyroid disease

- diabetes

- trouble urinating due to an enlarged prostate gland

- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you

- are taking the blood thinning drug warfarin

- are taking sedatives or tranquilizers

When using this product

- do not use more than directed

- excitability may occur, especially in children

- may cause drowsiness n alcohol, sedatives, and tranquilizers may increase drowsiness

- avoid alcoholic drinks n be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- redness or swelling is present

- new symptoms occur
- you get nervous, dizzy, or sleepless n pain or nasal congestion gets worse or lasts for more than 7 days
- fever gets worse or lasts for more than 3 days

If pregnant or breast-feeding,

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

Keep out of reach of children.

Keep out of reach of children. In case of overdose, contact a Poison Control Center (1-800-222-1222) immediately.

Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- Do not use more than directed
- Adults and children 12 years of age and older: take 2 tablets every 6 hours. Do not take more than 12 tablets in 24 hours.
- Children under 12 years of age: do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store at room temperature in a dry place
- do not use if blister package is torn.

Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid

Questions and comments?

1-888-952-0050 Monday through Friday 9 AM - 5 PM EST

Principal Display Panel



XL-3 Cold Medicine

COLD MEDICINE

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63654-275
Route of Administration	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	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	AZ;275
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-275-20	2 in 1 CARTON	11/15/2011	
1		10 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 Drug	M012	11/15/2011	

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

