

**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.

XL3 Cold

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 taking a 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 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 ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ 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 ■ pain or nasal congestion gets worse or lasts for more than 7 days ■ fever gets worse or lasts for more than 3 days

Keep out of reach of children

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or 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 4 hours. Do not take more than 12 tablets in 24 hours ■ Children under 12 years of age: do not use in children under 12 years of age; this will provide more than the recommended dose (overdoses) 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

alcohol, croscarmellose sodium, hypromellose, lactose monohydrate (derived from milk), magnesium stearate, polyethylene glycol, purified water, talc, titanium dioxide

COLD MEDICINE XL3

acetaminophen chlorpheniramine maleate phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63654-605
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

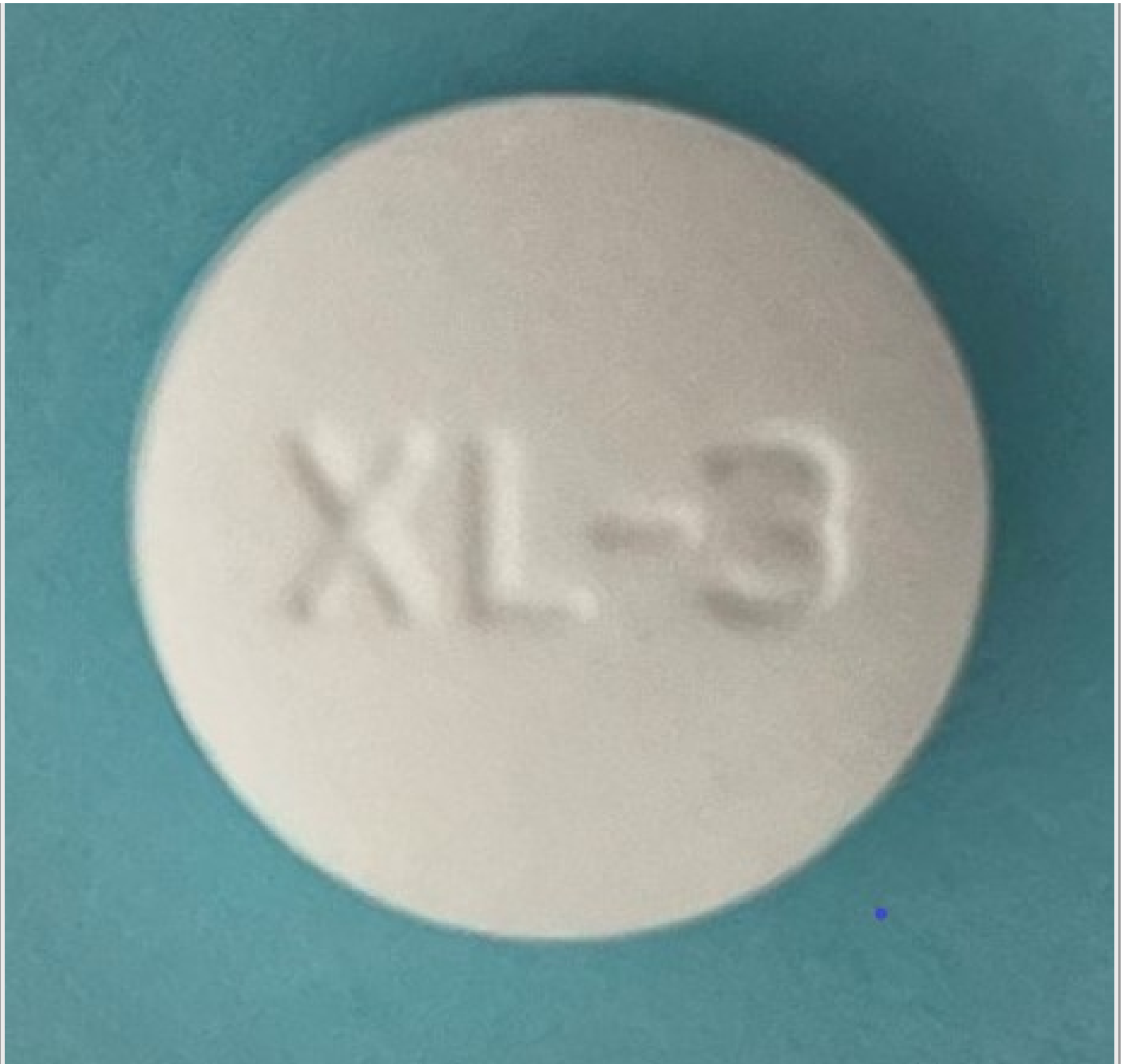
Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND (Tablet)	Size	11mm
Flavor		Imprint Code	XL3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-605-20	2 in 1 BOX	06/27/2022	
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 final	part341	06/27/2022	

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

Establishment

Name	Address	ID/FEI	Business Operations
Selder, S.A. de C.V.		824413629	manufacture(63654-605)