

**COLD MEDICINE XL3- acetaminophen chlorpheniramine maleate  
phenylephrine hydrochloride tablet  
Midway Importing, Inc.**

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**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 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 (overdoes) 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 monhydrate (derived from milk), magnesium stearate, polyethylene glycol, purified water, talc, titanium dioxide

### ***Questions and Comments?***

1-855-259-1590 Monday through Friday 9AM-5PM EST

# 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:76095-011
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

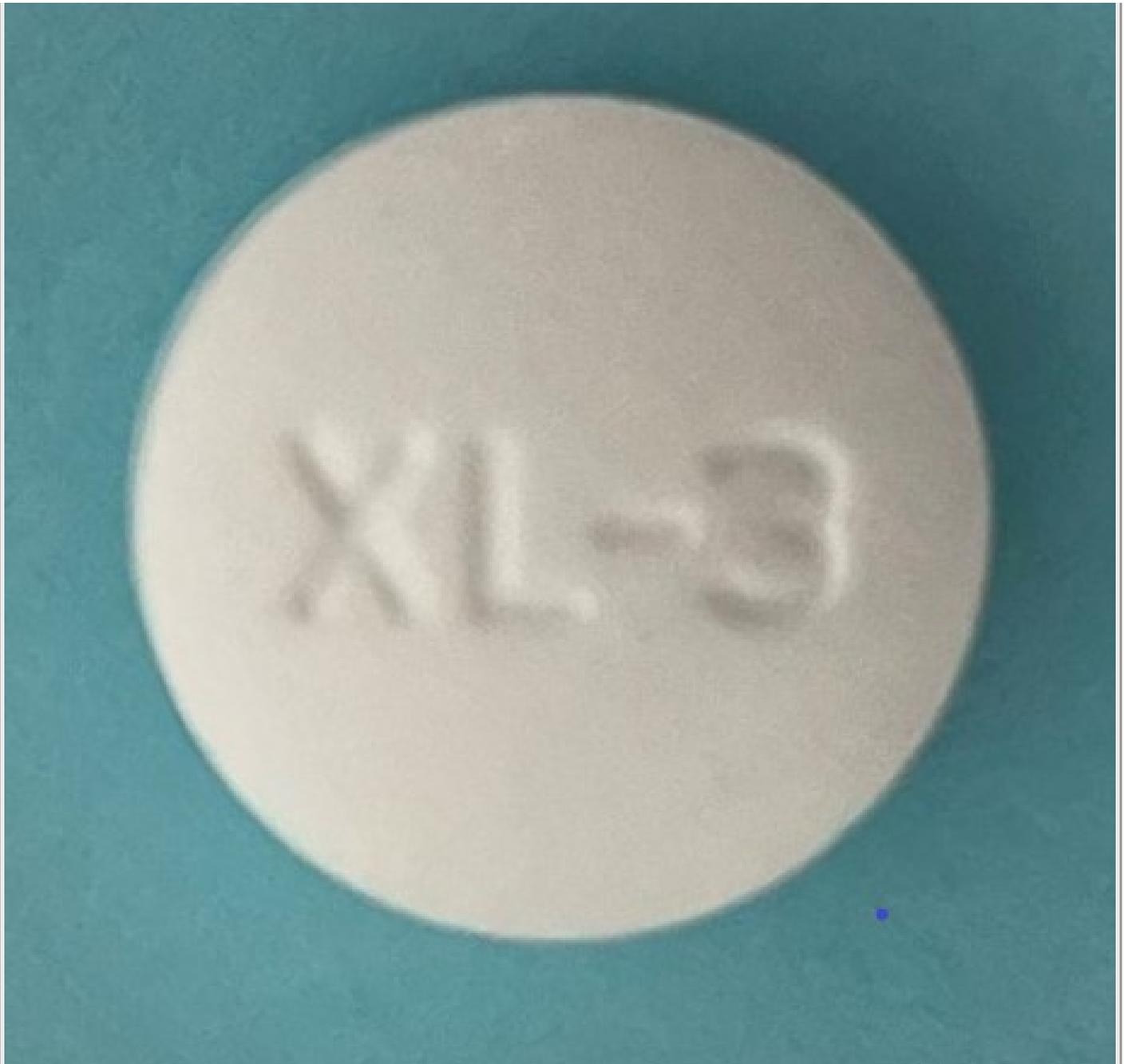
<b>Ingredient Name</b>	<b>Strength</b>
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CROSCARMELLOSE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

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76095-011-20	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 Drug	M012	06/27/2022	

**Labeler** - Midway Importing, Inc. (611851627)

### Establishment

Name	Address	ID/FEI	Business Operations
Selder, S.A. de C.V.		824413629	manufacture(76095-011)