

**COLD MEDICINE XL3 FORTE- acetaminophen chlorpheniramine maleate  
phenylephrine hydrochloride tablet  
Selder, S.A. de C.V.**

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**XL3FrteactmnpnhchlprhnmnpnhnylphrinhclSldr**

***Active ingredients (in each tablet)***

Acetaminophen 325 mg  
Chlorpheniramine maleate 4 mg  
Phenylephrine HCl 10 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 6 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 ■ for more than 3 days for fever 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. Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick 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 (see overdose warning)** ■ 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 ■ Children under 12 years of age: do not use because this product contains too much medication for children under this age.

### **Other Information**

■ store at room temperature 59-86F (15-30C) ■ do not use if package is torn or damaged

### **Inactive Ingredients**

Lactose monohydrate (derived from milk), Stearic acid, Povidone, Alcohol, Water purified, Hypromellose, Titanium dioxide, Triacetin, contains FDC Yellow No. 5 (tartrazine) as color additive

## Questions and Comments?

You may report side effects to 1-855-259-1590 Monday through Friday 9AM-5PM EST

## Package Label

**DO NOT USE IF STRIPE IS TORN OR DAMAGED**

Actual size  
\*Trade mark

FEVER - ACHES & PAINS - SNEEZING  
NASAL CONGESTION - RUNNY NOSE

**Fast and Strong relief of:**

Acetaminophen 325 mg  
Chlorpheniramine maleate 4 mg  
Phenylephrine HCl 10 mg  
Pain reliever / fever reducer  
Antihistamine  
Nasal decongestant

**COLD MEDICINE**

**XL3 FORTE**

**4 Tablets**

Drug Facts	
Active ingredients (in each tablet)	Purposes
Acetaminophen 325 mg	Pain reliever / fever reducer
Chlorpheniramine maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant
<b>Uses</b> temporarily relieves ■ minor aches and pains ■ headaches ■ nasal congestion ■ sinus congestion & pressure ■ runny nose ■ sneezing	
<b>Warnings</b>	
<b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 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.	
<b>Allergy alert:</b> 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. ▶	

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Lot. Exp. Date.

**COLD MEDICINE**

**TAKE ONE TABLET EVERY 4 HOURS**

### Drugs Facts (continued)

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**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.

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**Other information** ■ store at room temperature to 15°-30°C (59°-86°F) ■ do not use if package is torn or damaged.

**Inactive ingredients:** Lactose monohydrate (derived from milk), Stearic acid, Povidone, Alcohol, Water purified, Hypromellose, Titanium dioxide, Triacetin, contains FD&C Yellow No. 5 (tartrazine) as color additive.

**Question and Comments?** You may report side effects to 1-855-259-1590 Monday through Friday 9 AM - 5 PM EST.

Distributed by: Midway Importing, Inc  
1807 Brittmoores Road, Houston, TX 77043  
Made in Mexico

## COLD MEDICINE XL3 FORTE

acetaminophen chlorpheniramine maleate phenylephrine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63654-601
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	yellow (light yellow)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Tablet)	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	XL3;FORTE
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-601-50	50 in 1 BOX	08/01/2017	
1	NDC:63654-601-04	4 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:63654-601-20	2 in 1 BOX	08/01/2017	
2	NDC:63654-601-02	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63654-601-10	1 in 1 BOX	10/12/2018	
3	NDC:63654-601-01	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	08/01/2017	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Selder, S.A. de C.V.		824413629	manufacture(63654-601)

Revised: 10/2024

Selder, S.A. de C.V.