

**COUGH AND COLD XL3 XTRA- acetaminophen chlorpheniramine maleate dextromethorphan hydrobromide phenylephrine hydrochloride capsule, liquid filled  
Selder, S.A. de C.V.**

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**XL3LqijelActmnphnChlrphnrminDxtrmthrphnPhnylphrn**

***Active ingredients (in each capsule)***

**Acetaminophen 250 mg**

Chlorpheniramine Maleate 2 mg

Dextromethorphan Hydrobromide 10 mg

Phenylephrine HCl 5 mg

***Purpose***

**Pain reliever/fever reducer**

Antihistamine

Antitussive

Nasal decongestant

***Uses***

temporarily relieves: • muscular aches and pains • headache • temporarily reduces fever • runny nose • sneezing • itching of the nose or throat • itchy, watery eyes due to hay fever or other upper respiratory allergies • pressure • nasal congestion • cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants

***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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- 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
- for persistent or chronic cough such as occurs when smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor
- if you are taking sedatives or tranquilizers, without first consulting your doctor.

***Ask a doctor before use if you have***

- liver disease
- a breathing problem such as emphysema
- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you**

- are taking the blood thinning drug warfarin

**When using this product**

- excitability may occur, especially in children
- may cause drowsiness
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

**Stop use and ask a doctor**

- symptoms do not improve
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with a rash or a headache that lasts. These could be the signs of a serious condition
- nervousness, dizziness, or sleeplessness occur
- 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 the 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)** • do not take this product form more than 10 days unless directed by a doctor • Adults and children 12 years of age and over • take 2 capsule every 4 hours. • Do not take more than 12 capsules in 24 hours Children under 12 years of age • Do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdoes) may cause liver damage. **Do not exceed recommended dosage**

## ***Other information***

Store at room temperature to 15°-30°C (59°-86°F) • do not use if package is torn or damaged

## ***Inactive ingredients***

D&C red no. 33, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 600, polyethylene glycol 1000, povidone, propylene glycol, purified water

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

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

## **Package Label**



**Drug Facts**

Active ingredients (in each capsule)	Purposes
Acetaminophen 250 mg	Pain reliever / fever reducer
Chlorpheniramine Maleate 2 mg	Antihistamine
Dextromethorphan Hydrobromide 10 mg	Antitussive (cough suppressant)
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses** temporarily relieves • minor aches and pains • headache • temporarily reduces fever • runny nose • sneezing • itching of the nose or throat • itchy, watery eyes due to fever or other upper respiratory allergies • sinus congestion & pressure • nasal congestion • cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants.

**Warnings**  
**Liver warning**  
 This product contains acetaminophen. Severe liver damage may occur if you take • more than 12 capsules in 24 hours, which is the maximum daily amount for this product • 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** • with any other drug containing acetaminophen (prescription or nonprescription) • if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor • if you are allergic to acetaminophen or any of inactive ingredients in this product • 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 • for persistent or chronic cough such as occurs when smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor • if you are taking sedatives or tranquilizers, without first consulting your doctor.

**Ask a doctor before use if you have** • liver disease • a breathing problem such as emphysema or chronic bronchitis • glaucoma • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland.

**Ask a doctor or pharmacist before use if you** • are taking the blood thinning drug warfarin.

**When using this product** • excitability may occur, especially in children • may cause drowsiness • alcohol, sedatives, and tranquilizers may increase drowsiness effect • use caution when driving a motor vehicle or operating machinery • avoid alcoholic beverages.

**Stop use and ask a doctor if** • symptoms do not improve • pain, nasal congestion or cough gets worse or lasts for more than 7 days • redness or swelling is present • new symptoms occur • cough comes back or occurs with rash or headache that lasts. These could be signs of serious condition • nervousness, dizziness, or sleeplessness occur • fever gets worse or lasts for more than 3 days.

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

**Keep out of the reach of children.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of accidental 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) • Do not take this product for more than 10 days unless directed by a doctor • **Adults and children 12 years of age and over** • take 2 capsules every 4 hours • Do not take more than 12 capsules in 24 hours • **Children under 12 years of age** • Do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) may cause liver damage.  
**Do not exceed recommended dosage**

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

**Inactive ingredients** D&C red no. 33, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 600, polyethylene glycol 1000, povidone, propylene glycol, purified water.

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

## COUGH AND COLD XL3 XTRA

acetaminophen chlorpheniramine maleate dextromethorphan hydrobromide phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63654-800
<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	250 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	
<b>POLYETHYLENE GLYCOL 1000</b> (UNII: U076Q6Q621)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	blue (Sky Blue)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Soft liquid filled capsule)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	Xtra
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-800-20	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/15/2011	10/15/2018
2	NDC:63654-800-12	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/22/2014	
3	NDC:63654-800-06	6 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/15/2018	



### 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)

### Establishment

Name	Address	ID/FEI	Business Operations
Selder, S.A. de C.V.		824413629	label(63654-800)

Revised: 10/2024

Selder, S.A. de C.V.