

COLD MEDICINE XL3 FORTE- 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 Forte acetaminophen chlorpheniramine maleate phenylephrine hydrochloride tablet

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

COLD MEDICINE

XL-3 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
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.	



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Lot. Exp. Date.

COLD MEDICINE

TAKE ONE TABLET EVERY 4 HOURS

Drugs Facts (continued)
Do not use ■ if you are allergic to acetaminophen ■ 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 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 ■ 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.
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 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 Brittmoore Road, Houston, TX 77043
Made in Mexico

acetaminophen chlorpheniramine maleate phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63654-601
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	4 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

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

Product Characteristics

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

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-	10 in 1 BLISTER PACK; Type 0: Not a Combination		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	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)