

COUGH AND COLD XL3 XTRA- acetaminophen chlorpheniramine maleate dextromethorphan hydrobromide phenylephrine hydrochloride capsule, liquid filled
Progela, 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.

XL-3* Xtra Cold and Cough

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 if

- 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

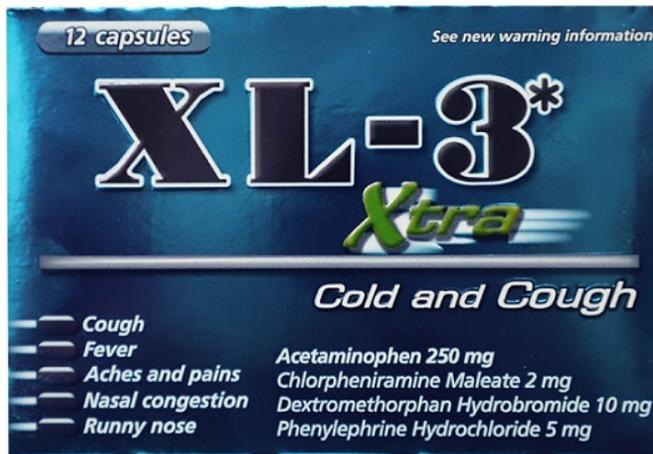
Inactive ingredients

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.
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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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:28623-250
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28623-250-01	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	03/01/2013	
2	NDC:28623-250-12	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/22/2014	
3	NDC:28623-250-06	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 final	part341	03/01/2013	

Labeler - Progela, S.A. de C.V. (812374932)

Establishment

Name	Address	ID/FEI	Business Operations
Progela, S.A. de C.V.		812374932	manufacture(28623-250)

Revised: 11/2022

Progela, S.A. de C.V.