

NOVEXCOLD- acetaminophen, pheniramine maleate, phenylephrine hcl powder, for solution
Herbion Pakistan (Pvt.) Ltd

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.

Active ingredient (in each packet)

Acetaminophen, 650 mg
Pheniramine maleate, 20 mg
Phenylephrine HCl, 10 mg

Purposes

Pain reliever / fever reducer
Antihistamine
Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains • minor sore throat pain • headache • nasal and sinus congestion • runny nose • sneezing • itchy nose or throat
- itchy, watery eyes due to hay fever
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours • 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.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Ask a doctor before use if you have

- liver disease • heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • trouble urinating due to an enlarged prostate gland • a breathing problem such as emphysema, or chronic bronchitis • a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers • taking the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

• nervousness, dizziness, or sleeplessness occurs • pain or nasal congestion gets worse or lasts more than 7 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health care professional before use.

Do not use

• in a child under 12 years of age • if you are allergic to acetaminophen
• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a pharmacist.
• 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.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. 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
• take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor

AGE	DOSE
Adults and children 12 years of age and over	One packet
Children under 12 years of age	Do not use

• dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10 - 15 minutes.
• if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains: Sodium** 9.37 mg
- Protect from heat and moisture.
- Do not use if printed packet is torn or punctured.
- Store between 68-77°F (20-25°C)

Inactive ingredients

Calcium phosphate, Citric acid, Lemon flavour, Malic acid, Sodium citrate, Sucrose, Titanium dioxide

Questions?

Call 1-888-(OK-HERBION) 654-3724, Monday through Friday, 9am - 5pm EST

NDC 44237-044-04

NovexCold

Flu & Sore Throat

Acetaminophen- Pain Reliever / Fever Reducer

Pheniramine Maleate- Antihistamine

Phenylephrine HCl- Nasal Decongestant

✓Nasal Congestion

✓Sore Throat

✓Headache

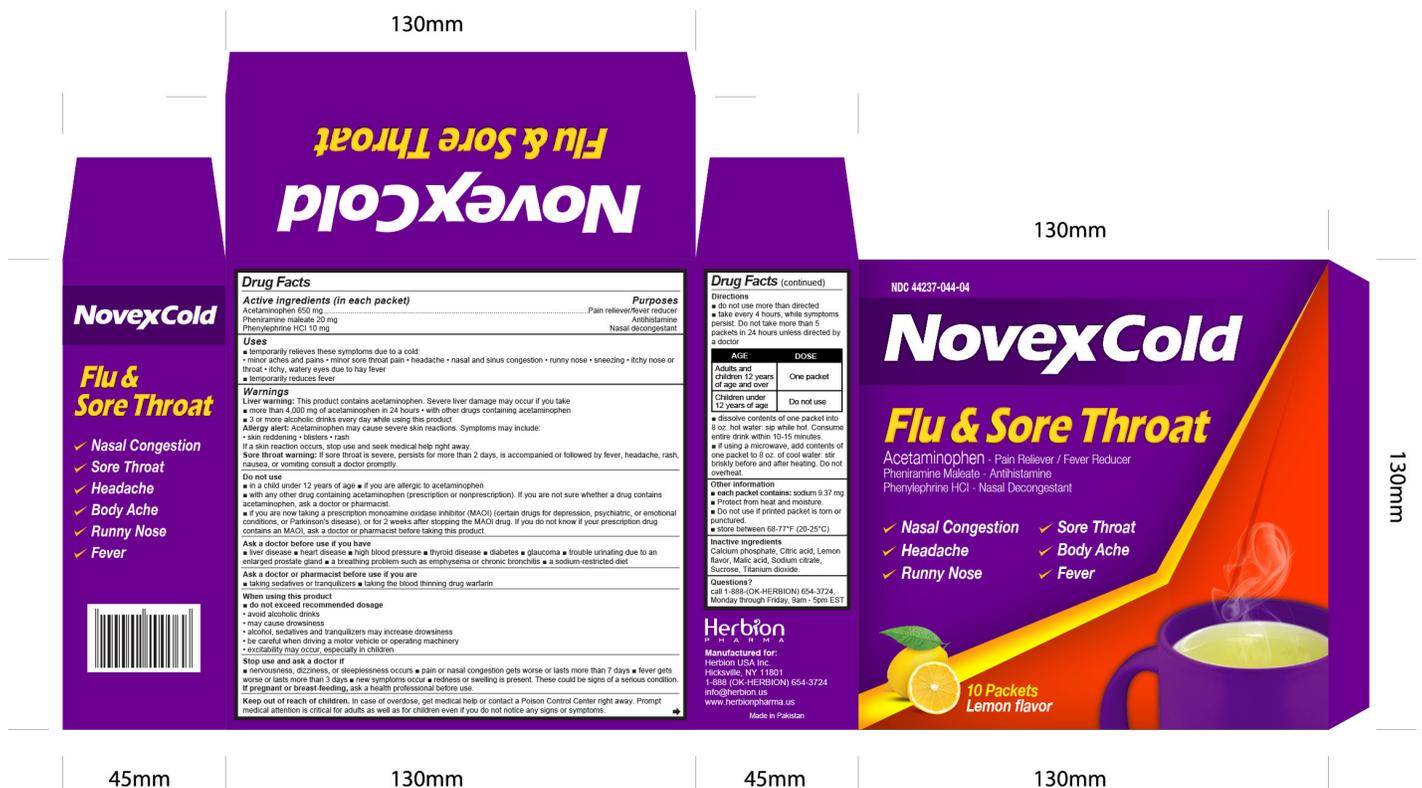
✓Body Ache

✓Runny Nose

✓Fever

10 Packets

Lemon flavor



NOVEXCOLD			
acetaminophen, pheniramine maleate, phenylephrine hcl powder, for solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-044
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 22 g	

PHENIRAMINE MALEATE (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9ZZ6M)	PHENIRAMINE MALEATE	20 mg in 22 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 22 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
CALCIUM PHOSPHATE, UNSPECIFIED FORM (UNII: 97Z1W3NDX)	
MALIC ACID (UNII: 817L1N4CKP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44237-044-04	10 in 1 CARTON	03/25/2020	
1		22 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/25/2020	

Labeler - Herbion Pakistan (Pvt.) Ltd (645482936)

Registrant - Herbion Pakistan (Pvt.) Ltd (645482936)

Establishment

Name	Address	ID/FEI	Business Operations
Herbion Pakistan (Pvt.) Ltd		645482936	manufacture(44237-044)