

**ACETAMINOPHEN, GUAIFENESIN, DEXTROMETHORPHAN HBR, PHENYLEPHRINE HCL- acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
OPMX LLC**

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.

Coldtac Severe

(Acetaminophen 325mg, Dextromethorphan HBr 10mg, Guaifenesin 200mg, Phenylephrine HCl 5mg Softgel)

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Guaifenesin 200mg

Phenylephrine HCl 5mg

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

- Take only as directed (See overdose warning)
- Do not exceed 4 doses per 24-hours
- Adults and children 12 years and over: take 2 softgels with water every 4 hours
- Children 4 to under 12 years: ask a doctor
- When using other Nighttime or Daytime products, carefully read each label to ensure correct dosing

Temporarily relieves common cold/flu symptoms:

- Nasal congestion
- Sinus congestion & pressure
- Cough due to minor throat & bronchial irritation
- Minor aches & pain
- Headache
- Fever
- Sore throat
- Reduces swelling of nasal passages
- Temporarily restore freer breathing through the nose
- Promotes nasal and/or sinus drainage
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hours, which is the maximum daily amount for this product with other drugs contains 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 doctor promptly

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
- 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.

Ask a doctor before use if you have:

Liver disease
High blood pressure
Thyroid disease
Diabetes
Trouble urinating due to enlarged prostate gland
Cough that occurs with too much phlegm (mucus)
Persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

When using this product, do not use more than directed.

Stop use and ask a doctor if:

You get nervous, dizzy, or sleepless
Pain, nasal congestion, or cough gets worse or lasts more than 7 days
Fever gets worse or last more than 3 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 a serious condition.

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

Keep out of reach of children.

Keep out of reach of children.

OVERDOSE WARNING: Read directions carefully. 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.

store at room temperature between 20-25°C (68-77°F)

avoid excessive heat and humidity



ACETAMINOPHEN, GUAIFENESIN, DEXTROMETHORPHAN HBR, PHENYLEPHRINE HCL

acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-782
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POVIDONE K30 (UNII: U725QWY32X)	
GELATIN (UNII: 2G86QN327L)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	orange (LIGHT ORANGE)	Score	no score
Shape	OVAL (Oblong)	Size	20mm
Flavor		Imprint Code	782
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-782-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/18/2019	

Labeler - OPMX LLC (029918743)