ACETAMINOPHEN DEXTROMETHORPHAN HYDROBROMIDE DOXYLAMINE SUCCINATE PHENYLEPHRINE HYDROCHLORIDE- acetaminophen dextromethorphan hydrobromide doxylamine succinate phenylephrine hydrochloride capsule, liquid filled
Granules India Limited

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.

Acetaminophen 325 mg
Dextromethorphan Hydrobromide 10 mg
Doxylamine Succinate 6.25 mg
Phenylephrine Hydrochloride 5 mg

Active ingredient

Acetaminophen 325 mg
Dextromethorphan hydrobromide 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine hydrochloride 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

• temporarily relieves these symptoms due to cold and flu:
sneezing
itching of the nose, throat or watery eyes due to hay fever
cough
nasal congestion
sinus congestion and pressure
sore throat
headache
minor aches and pains
runny nose
• helps clear nasal passages and shrinks swollen membranes
• temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take
• more than 10 softgels 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 warning

acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:
• skin reddening
• blisters
• rash
• hives
• facial swelling
• asthma (wheezing)
• shock
If a skin or allergic 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.

Do not use to sedate children.

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.
• if you ever had an allergic reaction to this product or any of its ingredients.
• in children 12 years of age.

Ask a doctor before use if you have

• liver disease
• heart disease
• high blood pressure
• thyroid disease
• diabetes
• glaucoma
• cough with excess phlegm (mucus)
• a breathing problem such as emphysema or chronic bronchitis
• difficulty in urination due to enlargement of the prostate gland
• persistent or chronic cough occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

• taking sedatives or tranquilizers
• taking a blood thinning drug warfarin

When using this product

• do not exceed recommended dose

• may cause marked drowsiness
• avoid alcoholic beverages
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving motor vehicles or operating machinery
• may cause excitability in children

Stop use and ask a doctor if

• pain, cough, or nasal congestion gets worse or lasts more than 7 days
• fever gets worse or lasts more than 3 days
• redness or swelling is present
• new symptoms occur
• cough comes back or occurs with rash or head ache that lasts for 1 week, these could be the signs of serious condition
• nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding

ask a health professional before use.

Keep out of the reach of children

In case of overdose, get medical help or contact Poison Control Center 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 take more than the recommended dose
adults & children under 12 years and over
- take 2 softgels with water every 4 hours.
- do not exceed 10 softgels in 24 hours or as directed by a doctor
children under 12 years

- do not use

Other information

• store in a cool and dry place.
• protect from sunlight.
• **Parents: Learn about teen medicine abuse, WWW.StopMedicineAbuse.org**

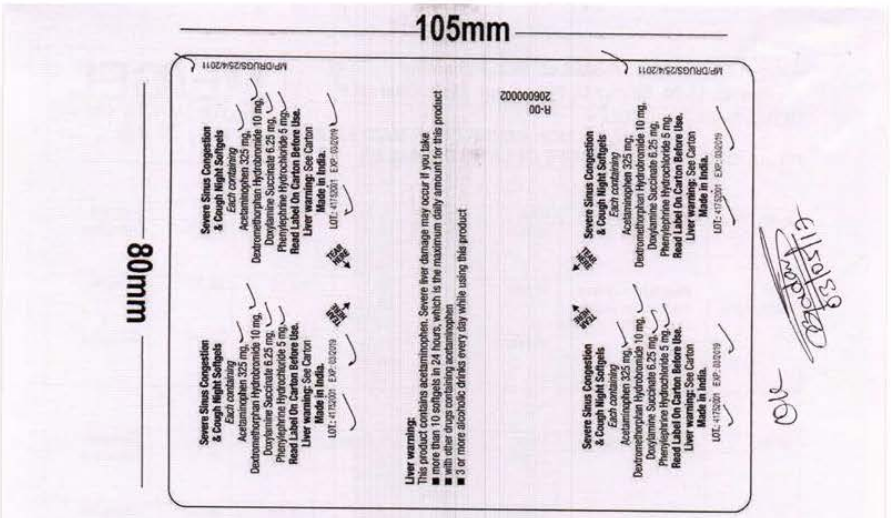
Inactive ingredients

FD&C blue 1, FD&C yellow 10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan, titanium dioxide.

Questions or comments?

call **1-877-770-3183** Mon-Fri 9:00 AM to 4:30 PM EST

Nighttime softgels



mm **Note: Ensure that the unvarnished area is not less than the minimum area specified or**

JOB INFORMATION	HISTORY			COLORS
ITEM#: DFT_BLISTER_80mmX105mm_SevereMucusCongestionReliefNight_R1 BLISTER TEMPLATE	LS	Version# 1 Printed		Black
CAD#:		Rev-1:	Rev-6:	
		Rev-2:	Rev-7:	
		Rev-3:	Rev-8:	
		Rev-4:	Rev-9:	
		Rev-5:	Rev-10:	Q.C.

GRANULES ARTWORK APPROVAL (THIS PROOF MUST BE SIGNED AND RETURNED) Job will not be released for production unless signed o

Name (print)	Signature

ATTENTION: PLEASE PROOFREAD CAREFULLY.

ed by a third party for Granules and is intended to represent the image prepared for you according to the instructions provided. Neither supplier nor G
either in format or content. This proof does not accurately represent colors that will print in the finished product. Any colors referenced on this proof
ed product will be printed to match the referenced Pantone® color or any other approved match standard established or provided by the supplier or
By signing this proof you are agreeing to these terms and authorizing its release into production under these conditions.

ACETAMINOPHEN DEXTROMETHORPHAN HYDROBROMIDE DOXYLAMINE

SUCCINATE PHENYLEPHRINE HYDROCHLORIDE

acetaminophen dextromethorphan hydrobromide doxylamine succinate phenylephrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-913
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POVIDONE (UNII: FZ989GH94E)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	G01
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62207-913-70	8 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2017	

Labeler - Granules India Limited (915000087)

Revised: 6/2017 Granules India Limited