

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride capsule, liquid filled
SOFTGEL HEALTHCARE PRIVATE LIMITED

Acetaminophen 325 mg, Dextromethorphan HBr 10mg and Phenylephrine HCl 5 mg Softgelatin Capsules

Active ingredient (in each Softgel)

Acetaminophen USP 325 mg

Dextromethorphan HBr USP 10 mg

Phenylephrine HCl USP 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

Temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

Warnings

Liver warning:

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

- more than 8 Softgels in 24 hrs, 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:

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.

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
- heart 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, 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 lasts 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

In case of overdose, get medical help or contact a 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

- take only as directed
- do not exceed 8 Softgels per 24 hrs

adults & children 12 years & over	2 Softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

Other information

- stored at 15° - 25°C (59° - 77°F)

Inactive ingredients

D&C yellow no. 10, gelatin, glycerin, polyethylene glycol 400, povidone k 30, propylene glycol, purified water, sorbitol sorbitan solution

<u>ACETAMINOPHEN 325MG, DEXTROMETHORPHAN HYDROBROMIDE 10MG,</u> <u>PHENYLEPHRINE HCL 5MG SOFTGELATIN CAPSULES</u> Each Soft Gelatin Capsule Contains: Acetaminophen USP 325mg, Dextromethorphan Hydrobromide USP 10mg, Phenylephrine Hcl USP 5mg		Imprint		
BATCH NO	:	NDC NO	:	35916 - 0917-1
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	
WARNING : KEEP OUT OF REACH OF CHILDREN				
<u>STORAGE</u> STORED AT 15° - 25°C (59° - 77°F)				
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.				
MANUFACTURED BY: SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO: XXXX		MANUFACTURED FOR		
CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"				

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0917
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C00X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	yellow (Transparent)	Score	no score
Shape	CAPSULE (oblong)	Size	24mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0917-1	2 in 1 CARTON	06/19/2025	
1		3000 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/19/2025	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (676666501)

Revised: 1/2026

SOFTGEL HEALTHCARE PRIVATE LIMITED