

**ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND
PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan
hydrobromide and phenylephrine hydrochloride capsule, liquid filled
Softgel Healthcare Pvt Ltd**

**Acetaminophen 325 mg, Dextromethorphan HBr 10mg and Phenylephrine HCl
5 mg Softgelatin Capsules (Day Time - Yellow)**

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 HBR 10MG AND PHENYLEPHRINE HCL 5MG SOFTGELATIN CAPSULES</u> Each Soft Gelatin Capsule Contains: Acetaminophen USP 325mg, Dextromethorphan HBr USP 10mg and Phenylephrine Hcl USP 5mg		IMPRINT		
BATCH NO	:	NDC NO	:	35916-0917-1
GROSS WT	:	MFG DATE	:	
NET WT	:	EXP DATE	:	
QUANTITY	:	SHIPPER NO.	:	
<u>WARNING : KEEP OUT OF REACH OF CHILDREN</u>				
<u>STORAGE</u> STORED AT 15°C -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 VILLAGE, KANCHEEPURAM, TAMILNADU 603 103, INDIA (IND) LABELLER CODE:35916 LIC NO:XXXX		MANUFACTURED FOR		
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING ONLY”				

**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

GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
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 Pvt Ltd (675584180)