

**ACETAMINOPHEN, DEXTROMETHORPHAN HBR AND DOXYLAMINE SUCCINATE-
acetaminophen, dextromethorphan hbr and doxylamine succinate capsule,
liquid filled
Softgel Healthcare Private Limited**

**Acetaminophen 325 mg, Dextromethorphan HBr 10 mg, Doxylamine
Succinate 6.25 mg Capsules (Night Severe)**

Active ingredients (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing

Warnings

Liver warning:

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

- more than 8 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:

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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

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 use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- do not exceed 25°C

Inactive ingredients

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K-30, propylene glycol, purified water, sorbitol sorbitan solution

Bulk Package Label

<p align="center"><u>ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HBR 10 MG, DOXYLAMINE SUCCINATE 6.25 MG CAPSULES (NIGHT SEVERE)</u></p> <p align="center"><u>Each Soft Gelatin Capsule Contains:</u></p> <p align="center">(Acetaminophen 325 mg, Dextromethorphan HBr 10 mg, Doxylamine Succinate 6.25 mg)</p>				<div>IMPRINT</div>
BATCH NO	:	NDC NO	:	35916-0185-2
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	
<p align="center"><u>WARNING</u></p> <p align="center">KEEP OUT OF REACH OF CHILDREN.</p>				
<p align="center"><u>STORAGE</u></p> <p align="center">DO NOT EXCEED 25°C</p>				
<p align="center">THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.</p>				
<p>MANUFACTURED BY:</p> <p>SOFTGEL HEALTHCARE PVT. LTD.,</p> <p>SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM VILLAGE, KANCHEEPURAM, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO:XXXXX</p>		<p>MANUFACTURED FOR</p>		
<p align="center">CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</p>				

ACETAMINOPHEN, DEXTROMETHORPHAN HBR AND DOXYLAMINE SUCCINATE

acetaminophen, dextromethorphan hbr and doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0185
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	green (Transparent)	Score	no score
Shape	CAPSULE (Oblong)	Size	22mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0185-2	3000 in 1 POUCH; Type 0: Not a Combination Product	05/17/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/17/2025	

Labeler - Softgel Healthcare Private Limited (675584180)