

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND DOXYLAMINE SUCCINATE- acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule, liquid filled
SOFTGEL HEALTHCARE PRIVATE LIMITED

Acetaminophen 325mg, Dextromethorphan Hydrobromide 10mg & Doxylamine Succinate 6.25 mg Capsules (Minis, Ultra-concentrated, Green)

Active Ingredients (in each capsule)

Acetaminophen USP 325 mg
Dextromethorphan HBr USP 10 mg
Doxylamine Succinate USP 6.25 mg

Purposes

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses

- temporarily relieves these symptoms due to a cold or flu :
- minor aches and pains • headache • cough
- sore throat • nasal and sinus congestion
- temporarily reduces fever

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: 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 general 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

- 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 have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease • heart disease • high blood pressure
- thyroid disease • diabetes
- cough that occurs with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- 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 exceed recommended dosage

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 headache that lasts.

These could be signs of a serious condition.

- nervousness, dizziness, or sleeplessness occurs

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

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other Information

- store at room temperature. Avoid excessive heat above 40°C (104°F).

Inactive ingredients

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

Bulk package Label

<u>ACETAMINOPHEN 325 MG , DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND DOXYLAMINE SUCCINATE 6.25 MG, CAPSULES (MINIS, ULTRA - CONCENTRATED, GREEN)</u>		Imprinted
Each Soft Gelatin Capsule Contains: (Acetaminophen USP 325 mg, Dextromethorphan HBr USP 10 mg & Doxylamine Succinate USP 6.25 mg)		
BATCH NO :	NDC NO :	35916-0189-1
MFG DATE :	GROSS WT :	
EXP DATE :	NET WT :	
QUANTITY :	SHIPPER NO. :	
<u>WARNING : KEEP OUT OF REACH OF CHILDREN</u>		
<u>STORAGE</u> STORE AT ROOM TEMPERATURE. AVOID EXCESSIVE HEAT ABOVE 40°C (104°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
<u>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</u>		

**ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND
DOXYLAMINE SUCCINATE**

acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0189
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
1,4-SORBITAN (UNII: AV0YTZ4E6J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	

Product Characteristics

Color	green (Glittering)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0189-1	1000 in 1 BAG; Type 0: Not a Combination Product	04/04/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M012	04/04/2025	
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Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (675584180)

Revised: 3/2025

SOFTGEL HEALTHCARE PRIVATE LIMITED