ACETAMINOPHEN 325MG, DEXTROMETHORPHAN HBR 10MG AND PHENYLEPRINE HCL 5MG- acetaminophen, dextromethorphan hbr and phenylephrine hcl capsule, liquid filled
Softgel Healthcare Private Limited

Acetaminophen 325mg, Dextromethorphan Hydrobromide 10mg, Phenylephrine Hydrochloride 5mg Capsules (Minis, Ultra-concentrated, Orange)

Active ingredients (in each softgelatin capsule)

Acetaminophen USP 325 mg

Dextromethorphan HBr USP 10 mg

Phenylephrine HCl USP 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

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 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 40ºC (104ºF).

Inactive ingredients

FD&C yellow no.5, FD&C yellow no.6, gelatin, glycerin, mica, polyethylene glycol 400, povidone K 30, purified water, sorbitol sorbitan solution, titanium dioxide

BULK PACKAGE LABEL

ACETAMINOPHEN 325 MG , DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND PHENYLEPHRINE HYDROCHLORIDE 5 MG, CAPSULES –MINIS-ULTRA CONCENTRATED, ORANGE Each Soft Gelatin Capsule Contains: (Acetaminophen USP 325 mg, Dextromethorphan HBr USP 10 mg & Phenylephrine HCl USP 5 mg)	Imprint

BATCH NO	:	NDC NO	:	35916-0188-1
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	

WARNING : KEEP OUT OF REACH OF CHILDREN

STORAGE
STORE AT ROOM TEMPERATURE. AVOID EXCESSIVE HEAT ABOVE 40ºC (104ºF).

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, PROCESSIING OR REPACKAGING"

ACETAMINOPHEN 325MG, DEXTROMETHORPHAN HBR 10MG AND PHENYLEPRINE HCL 5MG

acetaminophen, dextromethorphan hbr and phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35916-0188
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	orange (Glitter)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0188-1	1000 in 1 BAG; Type 0: Not a Combination Product	03/21/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/21/2025	

Labeler - Softgel Healthcare Private Limited (675584180)

Revised: 3/2025

Softgel Healthcare Private Limited