ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride capsule, liquid filled
Prodose, Inc.

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

ACETAMINOPHEN 325MG, DEXTROMETHORPHAN HYDROBROMIDE10MG, PHENYLEPHRINE HCL 5MG SOFTGELATIN CAPSULES

Each Soft Gelatin Capsule Contains:

Acetaminophen USP 325mg,Dextromethorphan Hydrobromide USP 10mg, Phenylephrine Hcl USP 5mg

IMPRINT

41

BATCH NO	:	NDC NO	:	68210-5053-1
GROSS WT	:	MFG DATE	:	
NET WT	:	EXP DATE	:	
QUANTITY	:	SHIPPER NO.	:	

WARNING: KEEP OUT OF REACH OF CHILDREN

STORAGE

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:

PRODOSE INC.,
2004 ORVILLE DRIVE NORTH
RONKONKOMA, NEW YORK (NY) 11779,
UNITED STATES (USA)

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:68210-5053
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**	41
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5053-1	2 in 1 CARTON	07/29/2025	
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	07/29/2025	

Labeler - Prodose, Inc. (119371190)

Revised: 7/2025 Prodose, Inc.