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

Acetaminophen 325 mg , Dextromethorphan Hydrobromide 10 mg, Doxylamine Succinate 6.25 mg and Phenylephrine Hydrochloride 5 mg (Night Mini Green)

Active ingredients (in each Capsule)

Acetaminophen USP 325 mg

Dextromethorphan Hydrobromide USP 10 mg

Doxylamine Succinate USP 6.25 mg

Phenylephrine Hydrochloride USP 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves these symptoms due to cold/flu:

- minor aches and pains
- headache
- nasal and sinus congestion
- cough
- sore throat
- runny nose
- sneezing
- 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 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 to sedate children.

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
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlaragement 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
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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 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 4 capsules in 12 hours or as

directed by a doctor.

- children under 12 years: do not use

Other information

Store at 15ºC- 25ºC (59º-77ºF)

Inactive ingredients

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

Bulk Label

ACETAMINOPHEN 325MG, DEXTROMETHORPHAN HBR 10MG, DOXYLAMINE SUCCINATE 6.25MG AND PHENYLEPHRINE HCL 5MG SOFTGELATIN CAPSULES (NIGHT MINI GREEN) Each Soft Gelatin Capsule Contains: Acetaminophen 325mg,Dextromethorphan HBr 10mg, Doxylamine succinate 6.25mg and Phenylephrine Hcl 5mg	IMPRINT

BATCH NO	:	NDC NO	:	35916-0186-1
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

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING ONLY"

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate and phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35916-0186
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0186-1	2 in 1 BOX	06/11/2025	
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	06/11/2025	

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 6/2025 Softgel Healthcare Pvt Ltd