

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

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**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 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
- 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 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 15°C- 25°C (59°-77°F)

***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

<u><b>ACETAMINOPHEN 325MG, DEXTROMETHORPHAN HYDROBROMIDE 10MG, DOXYLAMINE SUCCINATE 6.25MG AND PHENYLEPHRINE HCL 5MG SOFTGELATIN CAPSULES (NIGHT MINI GREEN)</b></u> Each Soft Gelatin Capsule Contains: Acetaminophen 325mg, Dextromethorphan Hydrobromide 10mg, Doxylamine succinate 6.25mg and Phenylephrine Hcl 5mg		IMPRINT
BATCH NO :		NDC NO : 35916-0186 -3
GROSS WT :		MFG DATE :
NET WT :		EXP DATE :
QUANTITY :		SHIPPER NO. :
<b><u>WARNING : KEEP OUT OF REACH OF CHILDREN</u></b>		
<u><b>STORAGE</b></u> 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.		
<b>MANUFACTURED BY:</b> <b>SOFTGEL HEALTHCARE PVT. LTD.,</b> SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE:35916 LIC NO:XXXX		<b>MANUFACTURED FOR</b>
<b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING ONLY”</b>		

## ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0186
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	green (Glittering Opaque)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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		
2	NDC:35916-0186-2	2 in 1 BOX	09/25/2025	
2		2000 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:35916-0186-3	2 in 1 BOX	01/12/2026	
3		1500 in 1 BAG; 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 (676666501)