

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

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**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 40°C (104°F).

### **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

<u>ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HYDROBROMIDE 10 MG, PHENYLEPRINE HYDROCHLORIDE 5MG,CAPSULES (MINIS-ULTRA CONCENTRATED,ORANGE)</u> Each Soft Gelatin Capsule Contains: (Acetaminophen USP 325 mg, Dextromethorphan HBr USP 10mg, Phenylephrine HCl USP 5mg)		IMPRINT		
BATCH NO	:	NDC NO	:	35916-0188- 4
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	
<b>WARNING</b> KEEP OUT OF REACH OF CHILDREN.				
<b>STORAGE</b> 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 AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.				
<b>MANUFACTURED BY:</b> SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO:XXXXX		<b>MANUFACTURED FOR</b>		
<b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</b>				

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

acetaminophen, dextromethorphan hbr and phenylephrine hcl capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0188
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	orange (Glitter)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:35916-0188-1	1000 in 1 BAG; Type 0: Not a Combination Product	03/21/2025	
2	NDC:35916-0188-2	2 in 1 BOX	06/12/2025	
2		3000 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:35916-0188-3	2 in 1 BOX	09/25/2025	
3		2000 in 1 POUCH; Type 0: Not a Combination Product		

4	NDC: 35916-0188-4	2 in 1 BOX	01/13/2026	
4		1500 in 1 BAG; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012		03/21/2025	

**Labeler** - Softgel Healthcare Private Limited (676666501)

Revised: 1/2026

Softgel Healthcare Private Limited