

**ACETAMINOPHEN, DEXTROMETHORPHAN HBR ,GUAIFENESIN- acetaminophen,  
dextromethorphan hbr ,guaifenesin capsule, liquid filled  
Softgel Healthcare Pvt Ltd**

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**Acetaminophen 325 mg, Dextromethorphan HBr 10mg, Guaifenesin 200 mg  
Capsules (Day Severe)**

***Active ingredients (in each Softgel)***

Acetaminophen USP 325 mg

Dextromethorphan HBr USP 10 mg

Guaifenesin USP 200 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

***Uses***

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passage ways of bothersome mucus and make coughs more productive.

***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, chronic bronchitis, 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, cough get worse or last 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**

- store at no greater than 25°C

**Inactive ingredients**

FD&C blue no.1, FD&C red no. 40, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

**bulk-label**

<b><u>ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HBR 10 MG, GUAIFENESIN</u></b>		IMPRINT
<b><u>200 MG CAPSULES (DAY SEVERE)</u></b>		
Each Soft Gelatin Capsule Contains: (Acetaminophen USP 325 mg, Dextromethorphan HBr USP 10mg, Guaifenesin USP 200 mg)		
BATCH NO :	NDC NO :	35916-0184- 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 GREATER THAN 25°C		
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> <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:XXXXXX		<b>MANUFACTURED FOR</b>
<b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”</b>		

## ACETAMINOPHEN, DEXTROMETHORPHAN HBR ,GUAIFENESIN

acetaminophen, dextromethorphan hbr ,guaifenesin capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0184
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	

### Product Characteristics

<b>Color</b>	pink (Transparent)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Oblong)	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0184-2	3000 in 1 POUCH; Type 0: Not a Combination Product	05/17/2025	
2	NDC:35916-0184-3	2 in 1 BOX	09/25/2025	
2		2000 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:35916-0184-4	2 in 1 BOX	01/16/2026	
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	05/17/2025	

**Labeler** - Softgel Healthcare Pvt Ltd (676666501)

Revised: 1/2026

Softgel Healthcare Pvt Ltd