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

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 Package Label

ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HBR 10 MG, GUAIFENESIN 200 MG CAPSULES (DAY SEVERE)

Each Soft Gelatin Capsule Contains:

(Acetaminophen 325 mg, Dextromethorphan HBr 10mg, Guaifenesin 200 mg)

IMPRINT

BATCH NO	:	NDC NO	: 35916-0184-2
MFG DATE	:	GROSS WT	:
EXP DATE	:	NET WT	:
QUANTITY	:	SHIPPER NO.	:

WARNING

KEEP OUT OF REACH OF CHILDREN.

STORAGE

STORE AT NO GREATER THAN 25ºC

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED, REPACKEDAND 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:XXXXX

MANUFACTURED FOR

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"

ACETAMINOPHEN, DEXTROMETHORPHAN HBR ,GUAIFENESIN

acetaminophen, dextromethorphan hbr ,guaifenesin capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35916-0184
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	pink (Transparent)	**Score**	no score
Shape	CAPSULE (Oblong)	**Size**	22mm
Flavor		**Imprint Code**	
Contains			

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	

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 (675584180)

Revised: 5/2025 Softgel Healthcare Pvt Ltd