

**ACETAMINOPHEN, DEXTROMETHORPHAN HBR AND DOXYLAMINE SUCCINATE-
acetaminophen, dextromethorphan hbr and doxylamine succinate capsule,
liquid filled
Softgel Healthcare Private Limited**

**Acetaminophen 325 mg, Dextromethorphan HBr 10 mg, Doxylamine
Succinate 6.25 mg Capsules (Night Severe)**

Active ingredients (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 softgels in 24 hours, 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- do not exceed 25°C

Inactive ingredients

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

**ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND
DOXYLAMINE SUCCINATE 6.25 MG SOFT GELATIN CAPSULES**

IMPRINT

Each Soft Gelatin Capsules Contains:

(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg, Doxylamine Succinate USP 6.25 mg)

BATCH NO	:	NDC NO	:	35916-0185-2
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	

WARNING

KEEP OUT OF REACH OF CHILDREN.

STORAGE

DO NOT EXCEED 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.

MANUFACTURED BY:

SOFTGEL HEALTHCARE PVT. LTD.,
SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD,
PUDUPAKKAM, CHENGALPATTU,
TAMILNADU 603 103, INDIA (IND)

MANUFACTURED FOR:

LABELLER CODE : 35916
LIC NO : XXXX

CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”

**ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND
DOXYLAMINE SUCCINATE 6.25 MG SOFT GELATIN CAPSULES**

IMPRINT

Each Soft Gelatin Capsules Contains:

(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg, Doxylamine Succinate USP 6.25 mg)

BATCH NO	:	NDC NO	:	35916-0185-3
MFG DATE	:	GROSS WT	:	
EXP DATE	:	NET WT	:	
QUANTITY	:	SHIPPER NO.	:	

WARNING

KEEP OUT OF REACH OF CHILDREN.

STORAGE

DO NOT EXCEED 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.

MANUFACTURED BY:

MANUFACTURED FOR:

SOFTGEL HEALTHCARE PVT. LTD.,
SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD,
PUDUPAKKAM, CHENGALPATTU,
TAMILNADU 603 103, INDIA (IND)
LABELLER CODE : 35916
LIC NO : XXXX

CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”

<u>ACETAMINOPHEN 325 MG, DEXTROMETHORPHAN HYDROBROMIDE 10 MG AND DOXYLAMINE SUCCINATE 6.25 MG SOFT GELATIN CAPSULES</u>		IMPRINT
Each Soft Gelatin Capsules Contains: (Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg, Doxylamine Succinate USP 6.25 mg)		
BATCH NO :		NDC NO : 35916-0185-4
MFG DATE :		GROSS WT :
EXP DATE :		NET WT :
QUANTITY :		SHIPPER NO. :
<u>WARNING</u> KEEP OUT OF REACH OF CHILDREN.		
<u>STORAGE</u> DO NOT EXCEED 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.		
MANUFACTURED BY:		MANUFACTURED FOR:
SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE : 35916 LIC NO : XXXX		
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKAGING”		

ACETAMINOPHEN, DEXTROMETHORPHAN HBR AND DOXYLAMINE SUCCINATE

acetaminophen, dextromethorphan hbr and doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0185
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	

WATER (UNII: 059QF0KO0R)
GELATIN (UNII: 2G86QN327L)
POVIDONE K30 (UNII: U725QWY32X)
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics

Color	green (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:35916-0185-2	3000 in 1 POUCH; Type 0: Not a Combination Product	05/17/2025	
2	NDC:35916-0185-3	2 in 1 BOX	09/25/2025	
2		2000 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:35916-0185-4	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 Private Limited (676666501)