

DELSYM COUGH- dextromethorphan hydrobromide tablet
RB Health (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Delsym[®] Cough

Drug Facts

Active ingredient (in each caplet)

Dextromethorphan HBr 15 mg

Purpose

Cough suppressant

Use

temporarily relieves

- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the impulse to cough to help you get to sleep

Warnings

Do not use 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

- chronic cough that lasts such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. 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.

Directions

- dose as follows or as directed by a doctor
- adults and children 12 years of age and over:
take 2 caplets every 6 to 8 hours as needed, not to exceed 8 caplets in 24 hours
- children under 12 years of age:
do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

FD&C yellow no. 6 aluminum lake, hypromellose, isomalt, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, titanium dioxide

Questions?

1-866-682-4639

You may also report side effects to this phone number.

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
Made in India

PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton

MAXIMUM STRENGTH

NEW!

NDC 72854-351-20

Delsym[®]

COUGH

Dextromethorphan HBr (Cough Suppressant)

LASTS

UP

TO

8HR

DAY

OR

NIGHT

FAST

RELEASE

Actual Size

20 Caplets

For Ages 12+



DELSYM COUGH

dextromethorphan hydrobromide tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-351
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOMALT (UNII: S870P55O2W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	D
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-351-20	1 in 1 CARTON	07/01/2021	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2021	

Labeler - RB Health (US) LLC (081049410)