

COUGH MUCUS RELIEF DM- dextromethorphan hbr and guaifenesin tablet
Strive Pharmaceuticals Inc.

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.

Dextromethorphan HBr 20mg and Guaifenesin 400mg

Dextromethorphan HBr 20mg

Guaifenesin 400mg

microcrystalline cellulose, sodium starch glycolate, talc, colloidal silicon dioxide, magnesium stearate, polyvinyl povidone, maltodextrin, stearic acid

* May contain hydroxypropyl methylcellulose, polyethylene glycol

* take with a full glass of water

* swallow whole; do not crush, chew or dissolve

*do not take more than 6 tablets in 24 hours

adults and children 12 years of age and over

1 tablet every 4 hours

children under 12 years of age

Do not use

* temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold

* helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

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

* persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

* cough accompanied by too much phlegm (mucus)

When using this product do not use more than directed

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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Cough Suppressant

Expectorant

* store at room temperature 25°C (77°F) ; excursions permitted between 15°C - 30°C (59°F - 86°F)

0.216



IMMEDIATE RELEASE

NDC 70692-101-24

Mucus Relief^{DM}

24 tablets



expectorant/cough suppressant
controls cough/non-drowsy
thins & loosens mucus

actual size

Dextromethorphan HBr **20mg** each tablet
Guaifenesin **400mg** each tablet



IMMEDIATE RELEASE



IMMEDIATE RELEASE

NDC 70692-101-24

Mucus Relief^{DM}

24 tablets



expectorant/cough suppressant
controls cough/non-drowsy
thins & loosens mucus

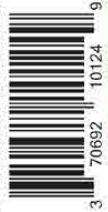
actual size

Dextromethorphan HBr **20mg** each tablet
Guaifenesin **400mg** each tablet

READ AND KEEP OUTER PACKAGE FOR
COMPLETE PRODUCT INFORMATION



Distributed by: STRIVE PHARMACEUTICALS INC.
East Brunswick, NJ
08816 • CT7069210124 • REV. 00-022020



3 70692 10124 9

Lot. No.:

Exp. Date:

Drug Facts (continued)

attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- take with a full glass of water
- swallow whole, do not crush, chew, or dissolve
- adults & children 12 years of age and over
 - 1 tablet every 4 hours.
 - do not take more than 6 tablets in 24 hours, unless directed by doctor
- children under 12 years of age
 - do not use

Other information

- store at room temperature between 20°C-25°C (68°F-77°F).
- avoid excessive heat and humidity.
- use cautiously after use.
- do not use if imprinted safety seal is broken or missing.

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, methocel K100, polyvinylpyrrolidone, sodium starch glycolate, stearic acid, lact. may contain

Questions or comments?

Call 1 (888) 577-8033

Drug Facts

Active ingredient (each tablet)
Dextromethorphan HBr 20mg.....Cough Suppressant
Guaifenesin 400mg.....Expectorant

Uses

- temporarily relieves cough, due to minor throat and bronchial irritation associated with the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

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, do not know if your prescription drug will interact with this product, ask a doctor or pharmacist before taking this product.

Ask a doctor if you have

- trouble breathing or too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product

- do not use more than directed

Stop use and ask a doctor if cough lasts more than 7 days, if you have a fever, if you have a headache, if you have a sore throat, if you have a rash, if you have chest-tightening, ask a health care professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately. OVERDOSE WARNING: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical



79425B

TABLETS
4
NDC: 70692-101-41

SoloPara
TOS
(COUGH)

Guaiifenesin 400mg, Dextromethorphan HBr 20mg

LOT: _____
EXP: _____

DRUG FACTS

Active Ingredients (in each tablet)	Purpose
Guaiifenesin 400 mg	Expectorant
Dextromethorphan HBr 20mg	Cough Suppressant

Uses:

- temporarily relieves cough due to minor (rhinitis and bronchitis) irritation associated with the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings:

Do not take

- 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

- persistent cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product:

- do not exceed recommended dosage.
- do not use for more than 7 days

Stop use and ask a doctor if

- cough lasts more than 7 days, recurs or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

LIFT PANEL FOR CONTINUED DRUG FACTS ▶

DRUG FACTS (Continued)

If pregnant or breast-feeding, ask a healthcare professional before use.

Keep out of reach of children. Overdose Warning: In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

• Take with a full glass of water	
• do not take more than 6 tablets in 24 hours.	
Adults and children 12 years of age & over	1 tablet every 4 hrs
Children under 12 years of age	Do not use

Other Information:

- Store at room temperature between 20-25°C (68-77°F).
- Store in a dry place.
- Avoid excessive heat.

Inactive Ingredients:

colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, polyvinyl povidone, purified water, sodium starch glycolate, stearic acid, talc

Questions Or Comments ?

1-833-665-9444

DRUG FACTS (Continued)

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Distributed By: O4 GLOBAL TRADING USA LLC., 2241 S Watson Rd, Suite 121 Arlington, TX 76010
www.onlyfor.com
Packaged By: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816.

TAMPER EVIDENT; DO NOT USE IF PACKAGE IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.

Four arrows point through foil

www.onlyfor.com CT2TOS4-REV.102018

dextromethorphan hbr and guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	16mm
Flavor		Imprint Code	S55
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-101-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2018	
2	NDC:70692-101-41	4 in 1 PACKAGE; Type 0: Not a Combination Product	12/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/15/2018	

Labeler - Strive Pharmaceuticals Inc. (080028013)

