EQUALINE CHEST CONGESTION RELIEF DM DM- dextromethorphan hydrobromide / guaifenes in tablet Supervalu 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.

DRUG FACTS

Active ingredient - (per tablet)

Dextromethorphan Hydrobromide 20mg

Guaifenesin 400mg

Purpose

Cough Suppressant

Expectorant

Uses

■ Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold

■ Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus

■ Helps make coughs more productive.

Warnings

Do not use ■ if you are now taking a prescription monoamine oxidase (inhiMor~MAIO) (Certain drugs for depression, psychiatric or emotional conditioners or Parkinson's disease)or for 2 weeks after stopping MAIO drug, If you do not know if your prescription drug contains an MAIO, ask your doctor or pharmacist before using this product.

Ask doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, bronchitis or emphysma
- cough is accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

- symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur.
- A persistent cough may be a sign 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 Center immediately.

Directions

- Adults and children 12 years of age and over:take 1 tablet every 4 hours as needed.
- Children 6 to 10 under 12 years of age: take 1/2 tablet every 4 hours as needed.
- Children under 6 years of age: consult a doctor.

Do not exceed 6 doses in a 24 hour period or as directed by a doctor

Other Information

Store at 15°-30°C (59°-86°F)

Inactive Ingredients magnesium stearate, microcrystalline cellulose. May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid.



EQUALINE CHEST CONGESTION RELIEF DM DM						
dextromethorphan hydrobromide / guaifenesin tablet						
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-114			
Route of Administration	ORAL					

Active Ingredier	nt/Active	Moiety				
	Ingredient Name				trength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)				DEXTROMETHORPHAN HYDROBROMIDE		20 mg
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)				Guaifenesin		400 mg
Inactive Ingredi	ents					
		Ingred	lient Name		Strength	
SILICON DIO XIDE (JNII: ETJ7Z	6XBU4)				
MAGNESIUM STEAR	ATE (UNII:	70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)						
MALTO DEXTRIN (UNII: 7CVR7L4A2D)						
STEARIC ACID (UNII: 4ELV7Z65AP)						
Product Charact	eristics					
Color		white	nite Score		2 pieces	
hape OVAL Size		Size	17mm			
Flavor			Imprint Code		PH0 73	
Contains						
Packaging						
# Item Code		Dackage Des	cription	Marketing Start Date	Markatir	ıg End Date
1 NDC:41163-114-50	1 in 1 C A B	Package Description			Marketii	
INDC.41103-114-30	1 in 1 CARTON 50 in 1 BOTTLE; Type 0: Not a Combination Product			00/01/2012		
1	50 III I DC	, 11EE, 19pc 0. 1001				
1						
1						
	formati	on				
1 Marketing Inf Marketing Categor			r Monograph Citation	Marketing Start Date	Marketi	ng End Date

Labeler - Supervalu Inc. (006961411)

Pharbest

Registrant - Reese Pharmaceutical Co (004172052)

Establishment							
Name	Α	ddress	ID/FEI	Business Operations			
Reese Pharmaceutical Co	0		004172052	relabel(41163-114) , repack(41163-114)			
T							
Establishment							
Name	Address		ID/FEI	Business Operations			

manufacture(41163-114)

557054835

Revised: 4/2014

Supervalu Inc.