GUIAFENESIN - guiafenes in tablet Sunrise Pharmaceutical 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.

Guaifenesin 400 mg Expectorant

OTC - ACTIVE INGREDIENT

Guaifenesin 400 mg.

OTC - PURPOSE

Expectorant.

INDICATIONS AND USAGE

Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and make coughs more productive.

WARNINGS

Ask a doctor before use if you have

Cough that lasts or chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Cough accompanied by too much phlegm (mucus)

OTC - STOP USE AND ASK A DOCTOR IF

Cough lasts for more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious illness.

OTC – IF PREGNANT OR BREAST FEEDING

Ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Take with a glass of water

Adults and children 12 years and over	1 tablet every 4 hour. Max 6 doses
Children 6 to under 12 years	Do not use
Children under 6 years	Do not use

OTHER INFORMATION

Store at 15(-30(C(59(-86(F)

INACTIVE INGREDIENT

Colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 11534-164-01	Purpose Expectorant	ome	oking,	signs	al I	tablet	ing or	bid	2	c
Guaifenesin 400mg		USES The point of the bronchial passageway of bothersome mucus and make coughs more productive	VarringS sk a doctor before use if you have persistent or chronic cough such as occurs with smoking, sthma, chronic bronchits, or emphysema trough accompanied by the much phegm (mucus)	a duroup in the more than 7 days, comes back, or occurs or persistent headache. These could be signs siss.	f pregnant or breast-leeding, ask a health professional professional professional professional professional overdoes, get medical help or contact a Poison Control Penter right away.	DirectionS a dults and children 12 years of age and older: take 1 t every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours. Thidren under 12 years of age: do not use	ther information do not use if imprinted safety seal under cap is missing or unaged	silicon dioxide, crocrystalline colate, stearic acid	16401	nisł
Expectorant	each tablet)	and thin t assagewa productive	have uch as occ emphysem uch phieg	ays, come adache. Th	ask a healt of children. contact a Po	of age and old of water while in 24 hours. e: do not use	seal und er	colloidal silic extrin, microc starch glycols	3411	Var
100 tablets	nt (in	USES The back of the process of the process of the brace secretions to rid the bronchial passageway mucus and make coughs more productive	use if you nic cough s nchitis, or e ed by too m	ore than 7 d	Heeding, a tof reach o	Iren 12 years of h a full glass of ceed 6 doses in 12 years of age:	ther information do not use if imprinted safety seal imaged store between 15-3070 (50-3675)	Inactive ingredients control a silicon dioxid magnesium stearde, mathodextin, microcrystalline cellulose, povidone, sodium starch gycolate, steari	115	10
	Drug Facts Active ingredient Suattenesin 400 mg	osen phleg s to rid the d make co	ngs octor before use if you tent or chronic cough chronic bronchitis, or accompanied by too	 coup use and ask of upon couph lasts for more than with fever, rash or persistent of a serious illness. 	f pregnant or breast-feeding, before use. Keep out of reach overdose, get medical help or Center right away.	ons and children ours with a o not excert	information	Inactive ingredien magnesium stearate, mal cellulose, povidone, sodiu	3	~
Sunrise Distributed by: Ptermover.tcal, Inc. Sunrise Pharmaceutical, Inc. Rahway, NJ 07065 USA www.sunriseoharma.com	9 9	Uses helps lo secretions mucus an	Warnings Ask a doctor persistent c asthma, chro cough acco	cough la with fever of a serior	If pregnant oefore use. overdose, g center right	Directions adults and chil very 4 hours w ensist Do note children under	damaged store be	Inactive nagnesium cellulose, p		Lot#: Evn Date:

guiafenesin tablet					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:115	34-164
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
	Ingredient Name		Basis of Str	rength	Strength
GUAIFENESIN (UNII: 495W7451V	Ingredient Name Q) (GUAIFENESIN - UNII:495W7451	VQ)	Basis of Str GUAIFENESIN	rength	Strength 400 mg
GUAIFENESIN (UNII: 495W7451V	0	VQ)		rength	-
	0	VQ)		rength	-
	0	VQ)		rength	-
	0	VQ)		rength	-
Inactive Ingredients	Q) (GUAIFENESIN - UNII:495W7451 Ingredient Name	VQ)		rength	400 mg
GUAIFENESIN (UNII: 495W7451V Inactive Ingredients SILICON DIO XIDE (UNII: ETJ7Z6 MAGNESIUM STEARATE (UNII:	Q) (GUAIFENESIN - UNII:495W7451 Ingredient Name 5XBU4)	VQ)		rength	400 mg
Inactive Ingredients SILICON DIOXIDE (UNII: ETJ7Z6 MAGNESIUM STEARATE (UNII: CELLULOSE, MICROCRYSTAL	Q) (GUAIFENESIN - UNII:495W7451 Ingredient Name SXBU4) 70097M6I30)	VQ)		rength	400 mg
Inactive Ingredients SILICON DIOXIDE (UNII: ETJ7Z6 MAGNESIUM STEARATE (UNII: CELLULOSE, MICROCRYSTAL	Q) (GUAIFENESIN - UNII:495W7451 Ingredient Name SXBU4) 70097M6I30)	VQ)		rength	400 mg
Inactive Ingredients SILICON DIOXIDE (UNII: ETJ7Z6 MAGNESIUM STEARATE (UNII: CELLULOSE, MICROCRYSTAL POVIDONE (UNII: FZ989GH94E)	Q) (GUAIFENESIN - UNII:495W7451 Ingredient Name SXBU4) 70097M6I30)			rength	400 mg

Pro	oduct Character	ristics					
Cole	or	WHITE	Scor	re		nc	o score
Sha	pe	ROUND	Size	!		13	3mm
Flav	/or		Imp	rint Code		T	CL;272
Con	itains						
Pac	ckaging						
	ckaging Item Code	Package Desc	cription	Marketin	g Start Date	Ma	arketing End Date
#		Package Desc 100 in 1 BOTTLE	cription	Marketin	g Start Date	Má	arketing End Date
#	Item Code		cription	Marketin	g Start Date	Ma	arketing End Date
#	Item Code		cription	Marketin	ig Start Date	Ma	arketing End Date
# 1	Item Code	100 in 1 BOTTLE	cription	Marketin	ig Start Date	Mi	arketing End Date
# 1 N M a	Item Code DC:11534-164-01	100 in 1 BOTTLE			g Start Date Marketing Star		arketing End Date Marketing End Date

Labeler - Sunrise Pharmaceutical Inc (168522378)

Registrant - Sunrise Pharmaceutical Inc (168522378)

Revised: 7/2013

Sunrise Pharmaceutical Inc