SAFETUSSIN PM- dextromethorphan doxylamine succinate liquid
Denison Pharmaceuticals, 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.

SAFETUSSIN PM

ACTIVE INGREDIENT

Active ingredients (in each 5ml tsp)	***Purpose***
Dextromethorphan HBr,USP 7.5 mg	Cough Suppressant
Doxylamine Succinate, USP 3.125 mg	Expectorant

USES

Cough Suppressant

Antihistamine

Keep out of reach of children

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

INDICATIONS & USAGE

- temporarily relieves coughgh • runny nose and sneezing

DOSAGE & ADMINISTRATION

age	dose
adults and children 12 years and over	4 teaspoons every 6 hours
children 4 to 12 years	ask a doctor
children under 4 years	do not use

aspartame,benzoic acid,citric acid,glycerin,menthol,methylparaben,natural peppermint flavor,propylene glycol,propylparaben
purified water

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 you use if you have:
- Asthma
- emphysema
- glaucoma
- excessive phlem (mucus)
- breathing problem
- chronic bronchitis
- persisten or chronic cough
- cough associated with smoking
- trouble urinating do to enlarged prostate gland
- a sodium restricted diet

ASK DOCTOR/PHARMACIST

If you are taking sedatives or tranquilizers.

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

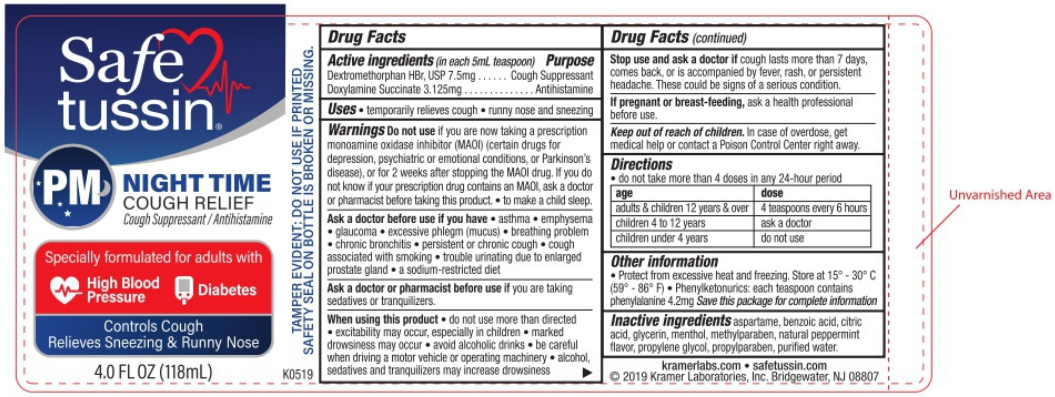
STOP USE

Ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of serious conditions.

OTHER INFORMATION
- Protect from excessive heat and freezing. Store at 15° - 30° C (59° - 86° F)
- Phenylketonurics: each teaspoon contains phenylalanine 4.2 mg

Safe this package for complete information

SAFETUSSIN PM (DEXTROMETHORPHAN DOXYLAMINE SUCCINATE) LIQUID



5.5 X 2.2596

CMYK

Revision #: K0519	**Drug Facts Font Size:** 6 & +	**Dimensions:** 1.5x 2.2596
Dates Created/Revised: 05/23/19		

Final Changes have been made and approved by:

Art Department: _____ Date: _____

Brand Manager: _____ Date: _____

Manufacturer: _____ Date: _____

Regulatory: _____ Date: _____

Kramer
LABORATORIES INC.
Miami, FL 33174
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SAFETUSSIN PM

dextromethorphan doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0295-5307
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 5 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	3.125 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINT (UNII: FV98Z8GITP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-5307-17	1 in 1 CARTON	01/01/2017	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0295-5307-28	1 in 1 CARTON	01/01/2017	11/07/2019
2		240 mL in 1 BOTTLE; 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	01/01/2017	

Labeler - Denison Pharmaceuticals, LLC. (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC.		001207208	manufacture(0295-5307)

Revised: 11/2019 Denison Pharmaceuticals, LLC.