

STONA- dextromethorphan hydrobromide lozenge
Sato Pharmaceutical Co., Ltd.

Stona Troche

Active ingredients (in each lozenge)
Dextromethorphan HBr 10mg

Purpose
Cough suppressant

Uses temporarily relieves cough due to minor throat and bronchial irritation associated with
■ a cold ■ inhaled irritants

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Do not use

■ this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

Ask a doctor or pharmacist before 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. A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

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.

Directions

Adults and children 12 years and older - Let 1 or 2 lozenges dissolve slowly in the mouth every 4 hours, not more than 12 lozenges in 24 hours.

Children 6 years to under 12 years - Let 1 lozenge dissolve slowly in the mouth every 4 hours, not more than 6 lozenges in 24 hours.

Children under 6 years - Ask a doctor

■ once or twice daily, preferably morning and evening, when needed or as directed by a doctor

■ start initial dosage with minimum dose, then adjust it to suit to bowel condition

Other information

■Phenylketonurics: Contains Phenylalanine (18.3mg) per lozenge.

Inactive ingredients aspartame, cetylpyridinium chloride, flavor, glycyrrhiza, hydroxypropyl cellulose, silicon dioxide, magnesium stearate, sucrose.

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STONA

dextromethorphan hydrobromide lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-301
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
LICORICE (UNII: 61ZBX54883)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SUCROSE (UNII: C151H8M554)	
ASPARTAME (UNII: Z0H242BBR1)	

Product Characteristics

Color	brown (pale brown)	Score	no score
Shape	ROUND	Size	14mm
Flavor	BLUEBERRY, GRAPE	Imprint Code	SATO;SATO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-301-01	1 in 1 CARTON	11/19/1995	
1		12 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 Drug	M012	11/19/1995	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-301) , label(49873-301) , pack(49873-301)

Revised: 11/2023

Sato Pharmaceutical Co., Ltd.