

STONA-S- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule
Sato Pharmaceutical Co., Ltd.

Stona-S Capsules

Active ingredients (in each capsule)

Acetaminophen 162.5 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan hydrobromide 10mg
Phenylephrine hydrochloride 5 mg

Purposes

Acetaminophen Pain reliever-fever reducer
Chlorpheniramine maleate Antihistamine
Dextromethorphan hydrobromide Cough suppressant
Phenylephrine hydrochloride Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold, the flu, or hay fever:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - runny nose
 - sinus congestion and pressure
 - cough due to minor throat and bronchial irritation
 - sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 capsules in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease). If you do not know whether a prescription drug contains an MAOI, ask a doctor or pharmacist.
- for 2 weeks after stopping the MAOI drug

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema,

or if cough is accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- may cause excitability especially in children
- do not drive or operate machinery
- avoid alcoholic beverages
- may cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- sore throat persists for more than 2 days
- nervousness, dizziness, or sleeplessness occur
- any of the following occurs (these could be signs of a serious condition):
- fever gets worse or or lasts more than 3 days
- a severe sore throat
- sore throat is accompanied or followed by high fever, headache, rash, nausea or vomiting
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

Do not give to children under 12 years of age unless directed by a doctor.

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

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

- adults and children 12 years of age and older: 2 capsules every 4 hours, while symptoms persist, not to exceed 6 doses (12 capsules) in 24 hours, or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- keep container tightly closed
- protect from light
- store between 15° to 30°C (59° to 86° F)
- each capsule contains calcium 10 mg

Inactive ingredients

dibasic calcium phosphate, FD and C Blue No. 2 Aluminum lake, FD and C Yellow No. 6, FD and C

Yellow No. 6 Aluminum lake, gelatin, magnesium stearate, microcrystalline cellulose, polysorbate 80, starch, talc, titanium dioxide, and wild cherry extract.

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	162.5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange, brown (pale yellow-brown)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor	CHERRY (WLD CHERRY EXTRACT)	Imprint Code	SATO;SATO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-113-01	1 in 1 CARTON	04/25/2014	
1		24 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 Drug	M012	09/27/2004	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-113) , label(49873-113) , pack(49873-113)

Revised: 12/2023

Sato Pharmaceutical Co., Ltd.