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

STONA TABLET

Active ingredients (in each tablet)
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 tablets 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.

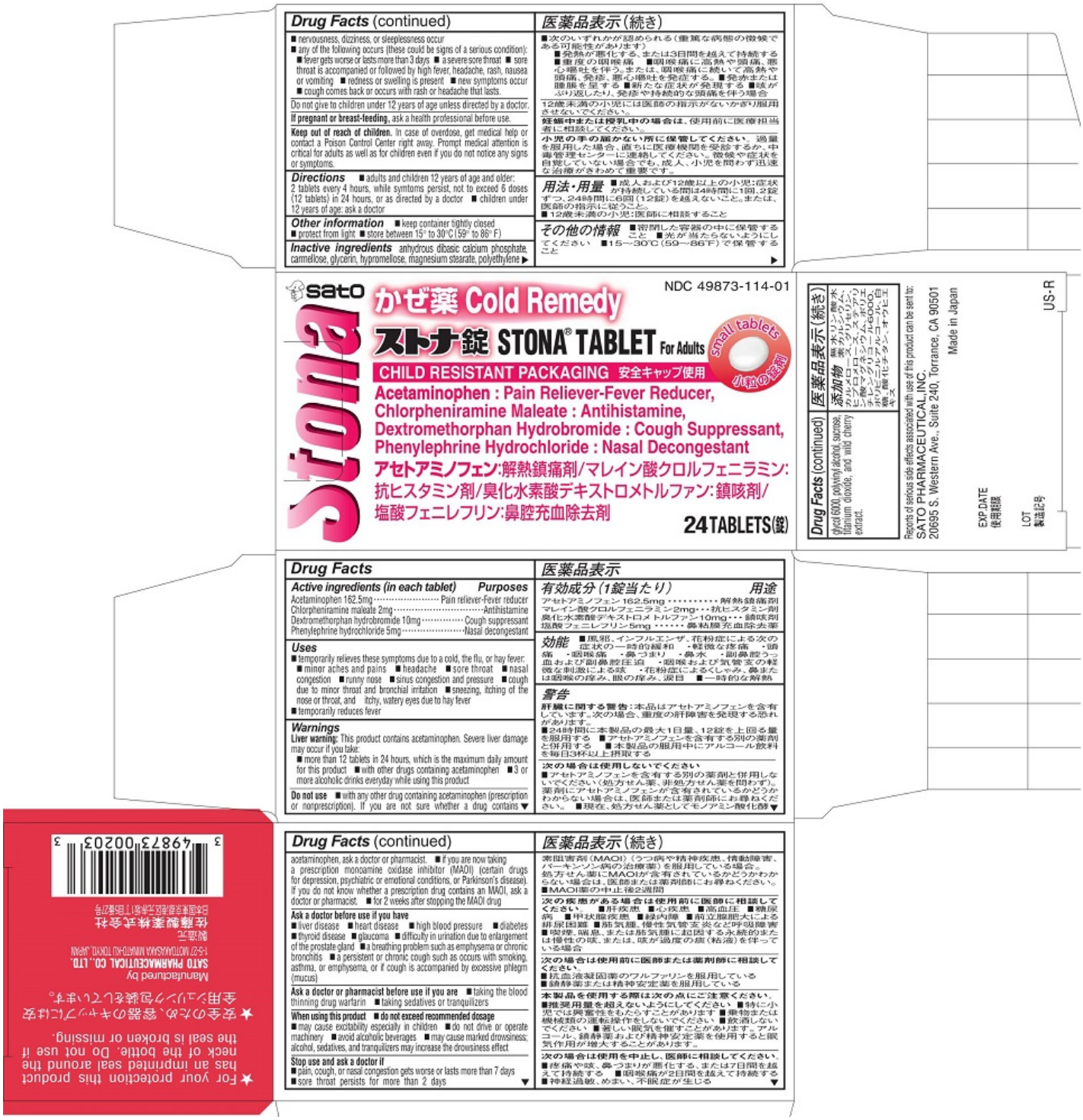
If pregnant or breast-feeding, ask a health professional before use.

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 tablets every 4 hours, while symptoms persist, not to exceed 6 doses (12 tablets) 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)

Inactive ingredients
anhydrous dibasic calcium phosphate, carmellose, glycerin, hypromellose, magnesium stearate, polyethylene glycol 6000, polyvinyl alcohol, sucrose, titanium dioxide, and wild cherry extract.



STONA

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-114
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor	CHERRY (WILD CHERRY EXTRACT)	**Imprint Code**	SATO;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-114-01	1 in 1 CARTON	09/29/2004	
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	09/29/2004	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-114)

Revised: 11/2023

Sato Pharmaceutical Co., Ltd.