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 tranguilizers

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 Alminum 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.

	Drug Facts (continued)	<u> 医薬品表示</u> (続き)		
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	Acetaminophen: Pain Chlorpheniramine Male Dextromethorphan Hyo Phenylephrine Hydrocl アセトアミノフェン:解熱鉛 抗ヒスタミン剤/臭化水素 鎮咳剤/塩酸フェニレフリ	CKAGING 安全キャップ使用 Reliever-Fever Reducer, eate : Antihistamine, frobromide : Cough Suppressant, hloride : Nasal Decongestant 強痛剤/マレイン酸クロルフェニラミン: 酸デキストロストルファン: ン:鼻腔充血除去剤	Drug Facts (continued) 医薬品表示(統含) FBC Bla No. 2 alminin kea. 添加物 際ネリテ酸本 FBC Bla No. 2 alminin kea. 添加物 際ネリテ酸本 FBC facing Nation No. 170 corne FED & Corne FED Stattion Inde Stati margasin Stattion The Stati Stati Stati Stati Stati Stati Distribati Stati Stati Stati Stati Stati Stati Stati Stati Stati Distribati Stati S	Reports of serious side efforts associated with use of this product can be sent to: SATO PHARMACEUTICAL, INC. 20095 S. Western Ave., Suite 240, Torrance, CA 90501 문자 DATE 使用現版 LOT NaLICE
	Drug Facts Active ingredients (in each capsule) Purposes Actaminghen 162 Smg Pain relevar-Fever reducer Cholpheniamire make/2 rmg Pain relevar-Fever reducer Cholpheniamire make/2 rmg Pain relevar-Fever reducer Detromethychan hydobrendio 10mg Cough suppressant Phenylephrine hydrochlande Smg Nasal decongestant Uses Image of the sine congestion and pressme Image on runny nee insine congestion and pressme Cough suppressant de to maior thural and branchial mittation sneeping, tiching of the nase of thuro, and it thry, water eyes due to hay fever Bemporarily reduces fever Warnings Liter warnings: Warnings They advaling This product contains acetaminophen. Severe liver damage may occur if you take: Naround it for this product ontains acetaminophen. Severe liver damage may occur if you take: In more thand 2 capakies in 24 hours, which is the maximum daily amount for this product with other drug containing acetaminophen. It is or a not prescription, if you are not sure whether a drug contains w	医薬品表示 有効成分(1カプセル当たり) 用途 アセトアシノフン102.5mg・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・		
 ★ Each capsule is protected by a band which bond she bond the bould the copsule or band is broken. ★ かきいひい protection this product the bottle. Do not use if capsule or band is broken or missing. ★ かうせいはバンドで封わさいてはお。 ★ かうせいはいていてくさいは、「はまない」 ★ かうせいはいていてくさい。 ★ かきのため、容器のキャップにはお ★ かうせいはいていたいです。 ★ からいひい protection this proven or missing. ★ かうせいはいていてくたいないでくたはか ★ かきのため、容器のキャップにはお ★ からいため、容器のキャップにはお ★ かきのため、容器のキャップにはお ★ からいため、容器のまかいです。 	Drug Facts (continued) adaminghen, as a obotr or plannacis. ■I you are now taking a prescription moneamite oxidase inhibitor (MADI) (ortain drugs for depression, psychittor or enformed ordinators, or Pakinson's dease). If you do not know whether a prescription drug contains an MADI, ask a doctar or pharmacist. If or 20 weeks after stopping the MADI drug Ask a doctor below usel if you have ■I yord disease ■ heard disease ■ bingh blood pressure ■ diabetes ■ thyred disease ■ bland disease ■ bingh blood pressure ■ diabetes ■ thyred disease ■ bland disease ■ bingh blood pressure ■ diabetes ■ thyred disease ■ bland disease ■ bingh blood pressure ■ diabetes ■ thyred disease ■ diseating problem sub = somtynama to chronic bronchitis ■ a persistent or chronic cough such as occars with snidking, asthma, or entryhsema, or if cough is accompanied by excessive phlagm (mouss) Ask a docter or pharmacit before use if you are ■ taking the blood thinning drug warfarin ■ taking sedstives or tranquileors When using this protict ■ do net exceed resommeried dowaleses actorkity exclusive, and tranquileurs mu, increase the drowaleses effect Stop use and sax a doctor if ■ an exclusive, and tranquileurs mu, increase the drowaleses effect Stop use and sax a doctor if ■ anan cough, or masil corogestion gets worse or lasts more than 7 days ■ sore throat persists for more than 2 days	医薬品表示(続き) 素明青剤(MAO)(ごつ病や精神疾患、情動障害、 パープレンスにMAC(増加)を増加している場合。 かったいまたいが常知している場合。 かったいまたいが常用時にお尋ねください。 MAO)率の中止後と週間 次の夜暖がある場合とは実育時にお尋ねください。 していまたいな常用時にお尋ねください。 していまたいな常用時には多くない。 ない、自行疾患、生心疾患、重素血症、増肥して くない、自行疾患、生心疾患、重素血症、増肥して くない、自行疾患、生心疾患、重素血症、増肥 がの保険のある場合とは使用前に医師よそなとい。 時に、自然力素にない、ない、自然力素のなどのない。 などの、またに、気が温度の感(的なたくない) していた。 たていたいたいたいで、 本型の多くない、自然力素の感にない。 などの場合に使用前に医師または薬剤師に相談して くためい。 本型の多く使用前に医師または薬剤師に相談して くため、 本型の多くない、自然力素の感にない。 素能のないたいたいたいで、 本型の多く使用する感は次の丸にここな思い。 素能のないたいたいたいで、 本型の多く使用する感にない。 素能のないたいたいたいで、 などの、またい、病情をないたい、 素能のないたいたいたい。 などのかられたいたいたいたい。 などの、またい、などのない、 素能のないたいたいたいで、 などの、またい、などのない、 素能のないたいたいたい。 などのかられたいたい。 などのかられたいたいたいたい。 などのかられたいたいたいたい。 などのかられたい、 などのかられたいたいたいたい。 本型の多くないたいたいたいたいたい。 などのかられたいたいたいたいたいたいたい。 などのかられたいたいたいたいたいたいたいたいたい。 などのかられたいたいたいたいたいたいたいたいたいたいたいたいたいたいたいたいたいたいたい		

STONA-S

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-113	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				

	Ingredient Name		Basis of St	rength	Strength	
ACETAMINOPHEN	JNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN				162.5 mg	
CHLORPHENIRAM UNII:3U6IO1965U)	E MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - CHLORPHENIRAMINE MALEATE				2 mg	
	DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) DEXTROMETHORPHAN HYDROBROMIDE					
PHENYLEPHRINE UNII:1WS297W6MV)	HENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINENII:1WS297W6MV)HYDROCHLORIDE				5 mg	
Inactive Ingre	dients					
	Ingredient Name			S	Strength	
CALCIUM PHOSPH	HATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)					
FD&C BLUE NO. 2	(UNII: L06K8R7DQK)					
ALUMINUM OXIDE	(UNII: LMI26O6933)					
FD&C YELLOW N	D. 6 (UNII: H77VEI93A8)					
GELATIN (UNII: 2G	36QN327L)					
	RATE (UNII: 70097M6I30)					
CELLULOSE, MICH	ROCRYSTALLINE (UNII: OP1R32D61U)					
POLYSORBATE 80	(UNII: 60ZP39ZG8H)					
STARCH, CORN (U	NII: 08232NY3SJ)					
TALC (UNII: 7SEV7J						
TITANIUM DIOXID	E (UNII: 15FIX9V2JP)					
Due duet Cherry						
Product Char						
	orange, brown (pale yellow-brown)		ore		no score	
Shape	CAPSULE	Size 19mr		1		
Flavor	CHERRY (WLD CHERRY EXTRACT)	Imprint Code SATO;S		;SATO		
Contains						
Packaging						
Packaging # Item Code	Package Description	Mar	keting Start Date		ting End ate	
	- ·	Mar 04/25/2	Date		-	
# Item Code 1 NDC:49873-113-			Date		-	
 # Item Code 1 NDC:49873-113- 01 	1 in 1 CARTON 24 in 1 BOTTLE; Type 0: Not a Combination		Date		-	
 # Item Code 1 NDC:49873-113- 01 1 	1 in 1 CARTON 24 in 1 BOTTLE; Type 0: Not a Combination		Date		-	
 # Item Code 1 NDC:49873-113- 01 1 	1 in 1 CARTON 24 in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2	Date	D	-	
 # Item Code 1 NDC:49873-113- 01 1 Marketing Marketing 	1 in 1 CARTON 24 in 1 BOTTLE; Type 0: Not a Combination Product Information Application Number or Monograph Citation	04/25/2 Ma	Date 014	D	ate eting End	

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)
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-113) , label(49873-113) , pack(49873-11

Revised: 12/2023

Sato Pharmaceutical Co., Ltd.