

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 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.

Drug Facts (continued)

■ nervousness, dizziness, or sleeplessness occur
 ■ any of the following occurs (these could be signs of a serious condition):
 ■ fever gets worse 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.

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医薬品表示 (続き)

■ 次のいずれかが認められる (重篤な病態の徴候である可能性があります)
 ■ 発熱が悪化する または3日間を超えて持続する
 ■ 重度の咽頭痛 ■ 咽頭痛に高熱や頭痛、悪心嘔吐を伴う または、咽頭痛に続いて高熱や頭痛、発熱、悪心嘔吐を伴う ■ 発熱または腫脹を伴う ■ 新たな症状が発現する ■ 咳がぶり返したり、発疹や持続的な頭痛を伴う場合

12歳未満の小児には医師の指示がない限り服用しないでください。
 妊娠中または授乳中の場合は、使用前に医療担当者にご相談してください。
 小児の手の届かない所に保管してください。過量を服用した場合、直ちに医療機関を受診するか、中毒管理センターに連絡してください。徴候や症状を自覚していない場合でも、成人、小児を問わず迅速な治療が必要となります。

用法・用量 ■ 成人および12歳以上の小児: 症状が持続している間は4時間に1回、錠剤ずつ、24時間以内(12錠)を超えないこと。または、医師の指示に従うこと。
 ■ 12歳未満の小児: 医師に相談すること

その他の情報 ■ 密閉した容器の中に保管してください ■ 15~30°C (59~86°F) で保管すること

NDC 49873-114-01

Stona

かぜ薬 Cold Remedy

ストナ錠 STONA® TABLET For Adults

CHILD RESISTANT PACKAGING 安全キャップ使用

Acetaminophen : Pain Reliever-Fever Reducer,
Dextromethorphan Hydrobromide : Cough Suppressant,
Phenylephrine Hydrochloride : Nasal Decongestant

アセトアミノフェン: 解熱鎮痛剤/マレイン酸クロルフェニラミン:
 抗ヒスタミン剤/臭化水素酸デキストロメトルファン: 鎮咳剤/
 塩酸フェニレフリン: 鼻腔充血除去剤

24 TABLETS (錠)

Drug Facts (continued)

typical OTC cough/colic, sore throat, nasal congestion, and mild cherry extract.

医薬品表示 (続き)

添加物 無水リン酸水素カルシウム、ヒドロキシプロピルセルロース、ステアリン酸マグネシウム、臭化水素酸デキストロメトルファン、フェニレフリン塩酸塩、ポリエチレングリコール、グリセリン、ヒドロキシプロピルメチルセルロース、ポリメチルシラン、チタニウム白

Reports of various side effects associated with use of this product can be sent to: SATO PHARMACEUTICAL, INC., 20695 S. Western Ave., Suite 240, Torrance, CA 90501

Made in Japan

EXP DATE 有効期限
 LOT 製造番号

US-R

Drug Facts

Active ingredients (in each tablet) Purposes

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Uses

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 ■ 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

医薬品表示

有効成分 (1錠当たり)

アセトアミノフェン 162.5mg 解熱鎮痛剤
 マレイン酸クロルフェニラミン 2mg 抗ヒスタミン剤
 臭化水素酸デキストロメトルファン 10mg 鎮咳剤
 塩酸フェニレフリン 5mg 鼻腔充血除去剤

効能 ■ 風邪、インフルエンザ、花粉症による次の症状の一次的緩和 ・ 軽微な疼痛 ・ 頭痛 ・ 咽頭痛 ・ 鼻づまり ・ 鼻水 ・ 副鼻腔炎 ・ 血および副鼻腔炎 ・ 咽頭痛および喉管炎の軽微な制薬による咳 ・ 花粉症によるくしゃみ、鼻または眼の痛み、目の痛み、涙目 ■ 一次的な解熱

警告

肝臓に関する警告: 本品はアセトアミノフェンを含有しています。次の場合、重度の肝障害を発現する恐れがあります。
 ■ 24時間内に本品の最大1日量、12錠を上回る量を服用する ■ アセトアミノフェンを含有する別の薬剤と併用する ■ 本製品の服用中にアルコール飲料を毎日3杯以上摂取する

次の場合は使用しないでください
 ■ アセトアミノフェンを含有する別の薬剤と併用しない (処方せん薬、非処方せん薬を問わず)。
 事前にアセトアミノフェンが含有されているかどうか分からない場合は、医師または薬剤師にお尋ねください。
 ■ 現在、処方せん薬としてモルグリン酸化糖

Drug Facts (continued)

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

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医薬品表示 (続き)

薬田毒剤 (MAOI) (うつ病や精神疾患、情動障害、パーキンソン病の治療薬) を服用している場合。処方せん薬にMAOIが含有されているかどうか分からない場合は、医師または薬剤師にお尋ねください。
 ■ MAOI薬の中止後2週間

次の疾患がある場合は使用前に医師に相談してください
 ■ 肝臓疾患 ■ 心疾患 ■ 高血圧 ■ 糖尿病 ■ 甲状腺疾患 ■ 腎臓病 ■ 前立腺肥大による排尿困難 ■ 肺気腫、慢性気管支炎など呼吸器疾患 ■ 咳、喘息、または肺気腫に起因する持続的または慢性的な咳、または、咳が過度の痰 (粘液) を伴っている場合

次の場合は使用前に医師または薬剤師に相談してください
 ■ 抗血液凝固薬のワルファリンを服用している
 ■ 鎮静薬または精神安定薬を服用している

本製品を使用する際は次の点にご注意ください。
 ■ 推奨用量を超えないようにしてください。■ 特に小児では興奮性をもちやすくなります。■ 薬物または機械類の運転操作をしないでください。■ 飲酒しないでください。■ 重い、眠気をおぼえることがあります。アルコール、鎮静薬および精神安定薬を使用すると眠気作用が増大することがあります。

次の場合は使用を中止し、医師に相談してください。
 ■ 疼痛や咳、鼻づまりが悪化する。または7日間を超えて持続する。■ 咽頭痛が2日間を超えて持続する。■ 神経過敏、めまい、不眠症が生じる

Drug Facts (continued)

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

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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

3 7 8 6 7 3 2 0 2 0 3 1 3

日本国東京都品川区東品川1丁目1番10号
佐藤製薬株式会社
製造元

1-87 MOTOMASAKI MINAMI-CHO, TORONTO, JAPAN
SATO PHARMACEUTICAL CO., LTD.
Manufactured by

★ 全用可能なキャップを装着しています。

★ 飲み水の容器のキャップを閉めてください。

★ For your protection this product has an imprinted seal around the neck of the bottle. Do not use if the seal is broken or missing.

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 (WLD 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.