

**STONA FOR CHILDREN- acetaminophen, chlorpheniramine maleate,
dextromethorphan hydrobromide syrup
Sato Pharmaceutical Co., Ltd.**

Stona Syrup for Children

Active ingredients (in 15 mL)

Acetaminophen 325mg

Chlorpheniramine maleate 2mg

Dextromethorphan hydrobromide 10mg

Purpose

Acetaminophen Pain reliever-fever reducer

Chlorpheniramine maleate Antihistamine

Dextromethorphan hydrobromide Cough suppressant

Uses

- For the temporary relief of the following cold symptoms
- minor aches and pains
- headache
- sneezing
- runny nose
- cough due to minor throat and bronchial irritation

- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen

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 your child is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- a breathing problem such as chronic bronchitis
- glaucoma
- liver disease

Ask a doctor or pharmacist before use if the child is

- taking sedatives or tranquilizers

- taking the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage
- may cause excitability in children
- may cause marked drowsiness
- sedatives and tranquilizers may increase the drowsiness effect

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

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 even if you do not notice any signs or symptoms.

Directions

- do not take more than 5 doses in any 24 hour period
- use only with enclosed measuring cup
- dose as follows while symptoms persist, or as directed by a doctor

children 6 to under 12 years of age: Take 15 mL every 4 hours

children under 6 years of age: do not use. ask a doctor.

This product does not contain directions or complete warnings for adult use

Other information

- keep container tightly closed
- store at room temperature (20-25 C or 68-77 F)

Inactive ingredients

alcohol, butylparaben, citric acid, FD&C Red No. 40, flavor, polyethylene glycol 1540, propylparaben, propylene glycol, saccharin sodium, sodium benzoate, sodium hydroxide, sucrose, water.

Questions or comments?

or to report serious adverse events associated with the use of this product call weekdays, 9 am - 5 pm at 1-310-787-1877 or write to the address on the front panel

Carton Image

sato NDC49873-108-01

STONA SYRUP FOR CHILDREN

Acetaminophen
-Pain Reliever-Fever Reducer
Chlorpheniramine Maleate
-Antihistamine
Dextromethorphan Hydrobromide
-Cough Suppressant

See new warnings information



Banana flavor

4 FL OZ (120 mL)

MANUFACTURED BY
SATO PHARMACEUTICAL CO., LTD.
1-5-27 MOTOAKASAKA MINATO-KU TOKYO, JAPAN
Reports of serious side effects associated with use of this product can be sent to:
SATO PHARMACEUTICAL, INC.
20695 S. Western Ave., Suite 240, Torrance, CA 90501



Other Information
Keep container tightly closed.
Store at room temperature (20°-25°C or 68°-77°F).
Inactive ingredients
alcohol, butylparaben, citric acid, FD&C Red No. 10, flavor, polyethylene glycol 1540, polyethylene glycol 400, saccharin sodium, sodium benzoate, sodium hydroxide, sucrose, water.
Questions or comments?
To report serious adverse events associated with the use of this product call weekdays, 9 am-5 pm at 1-810-767-1877 or write to the address on the front panel.

医薬品表示

有効成分・分量(15mL中) 配合目的
アセトアミノフェン25mg ……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アン10mg ……鎮咳剤

効能

■かぜに伴う下痢症状の一時的緩和
■軽度の痛み及び頭痛 ●くしゃみ
■発熱 ■鼻水 ■のどや気管支の炎症による咳
■一時的な解熱

使用上の注意

肝臓に関する注意:本品はアセトアミノフェンを含有しています。次の場合、重篤の肝障害を発現する恐れがあります。
■24時間に本製品の最大1日量、75mL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。

下記に該当する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でください(処方箋薬、非処方箋薬を問わず)。薬剤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。
■モノアミンオキシダーゼ阻害剤(MAOI)(うつ病、精神科、情緒不安定、パーキンソン病などで処方されることがある薬)を服用している時は、本剤を服用させないでください。また、MAOI製剤の服用を中止してから2週間以上本剤を服用させないでください。もし分からぬ場合には医師もしくは薬剤師にご相談ください。

下記症状がある小児には、服用前に医師にご相談ください。
■従気管支炎のような呼吸器疾患
■経口瘻 ■肝疾患

服用前に医師または薬剤師にご相談ください。
■小児が鎮痛剤、トランクワイザーを服用している場合
■小児が血液抗凝固薬ワーファリンを使用している場合

本剤使用の際、下記にご注意ください。
■推奨用量を超えないようご注意ください。
■小児には特に興奮作用があります。
■眠気をもよおすことがあります。
■鎮痛剤、トランクワイザーには眠気を増進させる作用があります。

下記症状の場合、服用を中止し、医師にご相談ください。
■嘔みや咳が悪化したり5日を超えて持続した場合
■熱が悪化したたり3日を超えて持続した場合
■発赤や浮腫が生じた場合
■新たな症状が生じた場合
■咳が再発するか、または持続する発疹や熱に伴って生じた場合、これらの症状は重篤な疾患の兆候の可能性があります。

小児の手のとどかない所に保管してください。誤って過量服用した場合、ただちに専門家または poison control センターへ連絡してください。過量服用した場合は、小児に症状があらわれなくても応急処置が必要となります。

用法・用量

■24時間に1回を超えて服用させないでください
■同様の計量カップは別は使用しないでください
■症状が継続している間は以下の通り、または医師の指示に従って服用させてください
6~11才の小児 1回15mLを4時間おきに服用
6才未満の小児 服用せず、医師にご相談ください
■この製品は大人の使用のための用法・用量や完全な注意事項は含まれていません

その他の情報

■密封して保管してください
■賞味(有効)期間は38(77°F)で保管してください

その他の成分 アルコール、ブチルパラベン、クエン酸、FD&C 赤色40号、香料、マクロゴール1540、プロピルパラベン、プロピレングリコール、サッカリンナトリウム、安息香酸ナトリウム、水酸化ナトリウム、精製白糖、精製水

お問い合わせ・ご意見 またはこの製品の古く使用による重篤な有害事象のご報告は下記または箱正面に記載の住所までお願ひ申し上げます。
電話 1-810-767-1877
受付時間 9:00~17:00(土・日・祝日を除く)

STONA SYRUP FOR CHILDREN

★ATTENTION

Do not purchase if the tape imprinted with the words "SATO HEALTHCARE INNOVATION" sealing the top and bottom of the box is damaged or missing. For your protection, this product has an imprinted seal around the neck of the bottle.

★FOR SAFETY

This product uses CHILD-RESISTANT SAFETY CAP TO OPEN. While pushing down, turn to counterclockwise.

sato NDC49873-108-01

ストナ こども用シロップ

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アン

-鎮咳剤

使用上の注意が新しくなりました



バナナ味

4 FL OZ (120 mL)

製造元 **佐藤製薬株式会社**
東京都港区元赤坂1丁目5番27号

重篤な副作用があらわれた場合は下記までご連絡ください。
SATO PHARMACEUTICAL, INC.
20695 S. Western Ave., Suite 240, Torrance, CA 90501

Drug Facts

Active ingredients (in 15 mL)

Purpose
Acetaminophen 325mg.....Pain reliever-fever reducer
Chlorpheniramine maleate 2mg.....Antihistamine
Dextromethorphan hydrobromide 10mg.....Cough suppressant

Uses

■for the temporary relief of the following cold symptoms
■minor aches and pains ■headache ■sneezing ■runny nose ■cough due to minor throat and bronchial irritation
■temporarily reduces fever

Warnings

Liver warning:This product contains acetaminophen. Severe liver damage may occur if your child takes:
■more than 5 doses in 24 hours, which is the maximum daily amount for this product
■with other drugs containing acetaminophen

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 your child is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has
■a breathing problem such as chronic bronchitis
■glaucoma ■liver disease

Ask a doctor or pharmacist before use if the child is
■taking sedatives or tranquilizers
■taking the blood thinning drug warfarin

When using this product

■do not exceed recommended dosage
■may cause excitability in children
■may cause marked drowsiness
■sedatives and tranquilizers may increase the drowsiness effect.

Stop use and ask a doctor if

■pain or cough gets worse or lasts more than 5 days
■fever gets worse or lasts more than 3 days
■redness or swelling is present
■new symptoms occur
■cough comes back or occurs with rash or headache that lasts.
These could be signs of a serious condition.

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 even if you do not notice any signs or symptoms.

Directions

■do not take more than 5 doses in any 24 hour period
■use only with enclosed measuring cup
■dose as follows while symptoms persist, or as directed by a doctor
children 6 to under 15mL every 4 hours
12 years of age do not use, ask a doctor
children under 6 years of age do not use, ask a doctor
■this product does not contain directions or complete warnings for adult use

EXP. DATE

使用期限

LOT

製造記号

US-F

STONA FOR CHILDREN

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide syrup

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49873-108

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BANANA (banana) , EGG NOG (sweet yogurt)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-108-01	1 in 1 CARTON	01/03/2001	
1		120 mL 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	01/03/2001	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-108) , label(49873-108) , pack(49873-108)

Revised: 12/2023

Sato Pharmaceutical Co., Ltd.