

**STONA COUGH- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet**  
**Sato Pharmaceutical Co., Ltd.**

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**Stona Cough Tablet**

**Active ingredients (in each tablet)**

Dextromethorphan hydrobromide 15mg

Guaifenesin 100 mg

Phenylephrine hydrochloride 5 mg

**Purposes**

Dextromethorphan hydrobromide Cough suppressant

Guaifenesin Expectorant

Phenylephrine hydrochloride Nasal decongestant

**Uses**

- for the temporary relief of cough and nasal congestion due to the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**Warnings**

**Do not use**

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease)
- for 2 weeks after the stopping the MAOI drug

**Ask a doctor before use if you have**

- heart disease ■ thyroid disease
- high blood pressure ■ high fever ■ diabetes
- difficulty in urination due to enlarged prostate gland
- cough accompanied by excessive phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug and do not know if it contains an MAOI

**When using this product**

- do not exceed recommended dosage

**Stop use and ask a doctor if**

- symptoms persist for more than 1 week or cough tends to recur (a persistent cough may be sign of a serious condition)
- nervousness, dizziness, or sleeplessness occur
- cough is accompanied by rash or persistent headache
- symptoms are accompanied by fever

**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.

### **Directions**

adults and children 12 years of age and over: take 2 tablets every 6 to 8 hours, not to exceed 8 tablets in 24 hours, or as directed by a doctor

children 6 to under 12 years of age: take 1 tablet every 6 to 8 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor

children under 6 years of age: ask a doctor

### **Other information**

- each tablet contains calcium 30 mg
- keep container tightly closed
- protect from light

### **Inactive ingredients**

ammonium hydroxide, anhydrous dibasic calcium phosphate, calcium carbonate, carmellose, carnauba wax, croscarmellose sodium, dewaxed orange shellac, , FDandC Yellow No. 6 aluminum lake as color additive, glycyrrhiza extract, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, partially hydrolyzed polyvinyl alcohol, polyethylene glycol 6000, propylene glycol, silicon dioxide, simethicone, sugar, talc, titanium dioxide

**Drug Facts (continued)**

**Other information**

- each tablet contains calcium 30mg
- keep container tightly closed
- protect from light

**Inactive ingredients**

camousoxium hydroxide, antihydroxide-dibasic calcium phosphate, calcium carbonate, carmellose, camousox wax, croscarmellose sodium, dewaxed orange shellac, FD&C Yellow No. 6 aluminum lake as color additive, glycyrrhiza extract, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, partially hydrolyzed polyvinyl alcohol, polyethylene glycol 6000, propylene glycol, silicon dioxide, simethicone, sugar, talc, titanium dioxide

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

**医薬品表示(続き)**

**その他の情報**

- 1錠中にカルシウム30mgを含有します。
- 光をしっかりと閉めてください。
- 直射日光を避けて保存してください。

**その他の成分**

水酸化アンモニウム、無水リン酸水素カルシウム、炭酸カルシウム、カルメロース、カルナウバロウ、クロスカルメロースナトリウム、セラック、FD&C黄色6号アルミニウムレーキ(着色料)、カンゾウエキス、ヒドロキシプロピルセルロース、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、結晶セルロース、ポリビニルアルコール(部分けん化)、ポリエチレングリコール6000、プロピレングリコール、二酸化ケイ素、シメチコン、白糖、タルク、酸化チタン

Manufactured by  
**SATO PHARMACEUTICAL CO., LTD.**  
 1-5-27 MOTOAKASAKA MINATO-KU TOKYO, JAPAN  
 製造元 佐藤製薬株式会社  
 日本国東京都港区元赤坂1丁目5番27号

**sato** **ストナ咳止錠** **STONA® COUGH TABLET**  
 CHILD RESISTANT PACKAGING 安全キャップ使用 **sugar-coated tablets** 糖衣錠  
**Dextromethorphan Hydrobromide: Cough Suppressant**  
**Guaifenesin: Expectorant**  
**Phenylephrine Hydrochloride: Nasal Decongestant**  
 臭化水素酸デキストロメトルファン: せき止め  
 グアイフェネシン: 去たん  
 塩酸フェニレフリン: 鼻づまり  
**24 TABLETS (錠)**  
 NDC 49873-306-01

**ストナ咳止錠** **STONA® COUGH TABLET**  
 EXP. DATE 有効期限  
 LOT 批発番号  
 US-Y

**Drug Facts**

**Active ingredients (in each tablet)**

Active ingredients	Purposes
Dextromethorphan hydrobromide 15 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine hydrochloride 5mg	Nasal decongestant

**Uses**

- for the temporary relief of cough and nasal congestion due to the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**Warnings**

- Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease)
- for 2 weeks after the stopping the MAOI drug
- Ask a doctor before use if you have:
  - heart disease
  - high blood pressure
  - diabetes
  - thyroid disease
  - high fever
  - difficulty in urination due to enlarged prostate gland
- cough accompanied by excessive phlegm (mucus) or persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**医薬品表示**

**有効成分・分量(1錠中)** 目的  
 臭化水素酸デキストロメトルファン15mg …… 鎮咳剤  
 グアイフェネシン100mg …………… 去痰剤  
 塩酸フェニレフリン5mg …………… 鼻炎消炎剤

**効能**

- 風邪に伴う咳、鼻づまりの改善
- たんや気管分泌液の除去

**使用上の注意**

- 下記に該当する方は、本品を服用しないでください。
- モノアミンオキシダーゼ阻害剤(MAOI)(うつ病、精神病、情緒不安定、パーキンソン病などの薬)を服用している時
- MAOI阻害剤の服用を中止してから2週間
- 下記症状のある人は服用前に医師にご相談ください。
- 心臓病 ■甲状腺疾患 ■高血圧 ■高熱時
- 糖尿病 ■前立腺肥大による排尿困難
- 多量の痰(粘液)を伴う咳 ■喫煙、喘息、慢性気管支炎、気腫などによる持続性または慢性的咳
- 下記に該当する人は、服用前に医師又は薬剤師にご相談ください。
- 服用中の薬にMAOIが含まれているかわからない人

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are taking a prescription drug and do not know if it contains an MAOI**

**When using this product**

- do not exceed recommended dosage
- Stop use and ask a doctor if:
  - symptoms persist for more than 1 week or cough tends to recur (a persistent cough may be sign of a serious condition)
  - nervousness, dizziness, or sleeplessness occur
  - cough is accompanied by rash or persistent headache
  - symptoms are accompanied by fever

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.

**Directions**

adults and children 12 years and over	take 2 tablets every 6 to 8 hours, not to exceed 8 tablets in 24 hours, or as directed by a doctor
children 6 to under 12 years of age	take 1 tablet every 6 to 8 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor
children under 6 years of age	ask a doctor

**医薬品表示(続き)**

本品服用の際、下記にご注意ください。

- 用法・用量を超えて服用しないでください。
- 下記の場合、服用を中止し、医師にご相談ください。
- 症状が1週間以上続いたり、咳が再発する場合(しつこい咳は重篤な症状の前兆の可能性ががあります)
- 神経過敏症、めまい、不眠が起こった場合
- 発疹、持続性の頭痛が伴う咳が出る場合
- 発熱を伴う場合
- 妊娠授乳中の方は本剤を服用前に、専門家にご相談ください。
- 小児の手の届かない所に保管してください。誤って過量を服用した場合、直ちに専門家又はポイズンコントロールセンターへご相談ください。

**用法・用量**

大人(12才以上)	1回2錠を6~8時間おきに服用。ただし24時間以内に8錠を超えて服用しないこと。または医師の指示に従うこと。
6才~12才未満	1回1錠を6~8時間おきに服用。ただし24時間以内に4錠を超えて服用しないこと。または医師の指示に従うこと。
6才未満	医師にご相談ください。

9 50690 22867 2  
 本製品の容器の蓋が破損しているか、または封入のシールが破損しているかを確認してください。破損している場合は、この製品を使用しないでください。破損している場合は、この製品を破損しているままに使用しないでください。破損している場合は、この製品を破損しているままに使用しないでください。

<b>STONA COUGH</b>			
dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49873-306
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>LICORICE</b> (UNII: 61ZBX54883)	
<b>HYDROXYPROPYL CELLULOSE</b> (UNII: RFW2ET671P)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	SATO;5
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-306-01	1 in 1 CARTON	11/24/2004	
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	11/24/2004	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-306)

Revised: 12/2023

Sato Pharmaceutical Co., Ltd.