

*Please store this instruction leaflet in a safe place for later reference.*

*Be sure to read the instructions carefully before use.*

## **SHONIYO SEKIDOME CHEWABLE**

小児用せきどめチュアブル

<COUGH AND EXPECTORANT REMEDY>

**“SHONIYO SEKIDOME CHEWABLE”** is cough and expectorant remedy for the relief of cough and sputum of children. Approved for use by children between 5 and 14 years of age.

### <PRODUCT FEATURES>

1. Chewable tablet which is administered by chewing without water
2. Easy-to-take chewable tablet with lemon soda flavor suitable for small children
3. Portable and individual package
4. Non-narcotic
4. Sugar-free
5. Caffeine-free

### **CAUTIONS FOR USE**

{SHONIYO SEKIDOME CHEWABLE is cough and expectorant remedy for children, common cautions as cough and expectorant remedies (cough medication) are described here.}

*[To be avoided!]*

(Failure to observe the following may result in the symptoms worsening or adverse reactions/accidents occurring.)

1. This medication should not be used the following persons:  
Persons who experience an allergic reaction to this medication, any component of this medication
2. This medication should not be used in combination with the following medications:  
Oral medicines containing other cough and expectorant remedies, cold remedies, sedatives, or antihistamines (oral medications for nasal catarrh, motion sickness, or anti-allergic agents, etc.)
3. Do not drive or operate machinery after using this medication. (It may cause drowsiness, etc.)

*[Consult a physician for the following]*

1. The following persons should consult a physician, pharmacist, or registered distributor of this medication before using this medication.

(1) A person undergoing medical treatment from a physician

(2) A pregnant woman or a woman suspected of being pregnant

(3) A mother who is breast-feeding a child

(4) An elderly person

(5) A person with a medical history of being allergic to medicines and other substances

(6) A person with the following symptoms:

High fever, difficulty in urination

(7) A person diagnosed as having the following:

Cardiac disease, hypertension, diabetes mellitus, glaucoma, thyroid disease

2. The following symptoms may be adverse reactions to this medication. If any of these symptoms occur, discontinue use immediately and consult a physician, pharmacist, or registered distributor of this medication. Take the instruction leaflet with you.

Related area	Symptoms
Skin	Rash, redness, itching
Digestive organs	Nausea, vomiting, loss of appetite
Central nervous system	Dizziness
Urinary system	Difficulty in urination

In very rare cases the following serious symptoms may occur. In this case, consult a physician immediately.

Symptom's name	Symptoms
Anaphylactoid symptoms	Occurrence of itching of skin, hives, hoarseness, sneezing, itching of throat, or breathing difficulties, etc. soon after use
Aplastic anemia	Bruising, nosebleed, gingival bleeding, fever, pale skin and mucus, fatigue, palpitation, shortness of breath, feel ill and dizzy, and appearance of blood in urine, etc.
Agranulocytosis	Sudden high fever, chill, throat pain, etc.

3. The following symptoms may appear with use of this medication. If these symptoms continue or worsen, discontinue use and consult a physician, pharmacist, or registered distributor of this medication. Take the instruction leaflet with you.

Dry mouth, drowsiness

4. Discontinue use when the cold symptoms do not improve after having used this medication 5 or 6 times, and consult a physician, pharmacist, or registered distributor of this medication. Take the instruction leaflet with you.

## INDICATIONS

Cough and sputum

## COMPOSITION (in 1 tablet)

Components	Content
Tipepidine hibenazate	3.125 mg
Noscapine	2.5 mg
<i>d,l</i> -Methylephedrine hydrochloride	3.125 mg
<i>d</i> -Chlorpheniramine maleate	0.25 mg

Additives: Hydrogenated maltose starch syrup, D-Mannitol, Potato starch, Calcium stearate, Calcium silicate, Hydroxypropylmethylcellulose acetate succinate, Ethyl acrylate • methyl methacrylate copolymer, Polyoxyethylene nonylphenyl ether, Aspartame (L-Phenylalanine compound), Ethanol, Tocopherol, *l*-Menthol, and flavor

### [Notes]

When using this medication, urine may sometimes turn red. There is no need for worry as this is due to the tipepidine hibenazate in it.

## DOSAGE AND DIRECTION

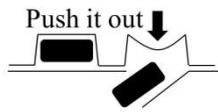
Take the following dosages by chewing or disintegrating in mouth.

Age	One dosage	Daily dosage
between 11-14 years	4 tablets	3 times daily after eating, and before bedtime if required.
between 8-10 years	3 tablets	
between 5-7 years	2 tablets	
Under 5 years	Do not use	

### [Cautions]

- (1) Please follow the recommended dosage and directions.
- (2) This medication should be given to children only under adult supervision.
- (3) As shown in the diagram, firmly push the convex portion of the PTP (Push Through Pack) sheet containing the tablet with the tip of one finger and break the aluminum film on the rear side. Remove the tablet. (Be careful to avoid swallowing a piece of the packaging sheet by mistake, doing so may injure the esophageal mucosa.)

<How to remove the tablet>



### **CAUTIONS ON HANDLING AND STORAGE**

- (1) Store in a sealed container in a cool, dry place free from direct sunlight.
- (2) Keep all medication out of the reach of children.
- (3) Do not transfer this medicine to a different container. (It may be misused or the quality may deteriorate.)
- (4) Do not break the aluminum film on the rear side unless using the tablet, as doing so may cause the deterioration in the quality of this medication.
- (5) Do not exceed the period of use.