Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 03/2015

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Mucosolvan Tablet 15mg

Active ingredient: Ambroxol hydrochloride

Dosage form: white tablet, diameter: approximately 7.0 mm

Print on wrapping:ムコソルバン 15mg

Effects of this medicine

This medicine increases pulmonary/respiratory secretions and promotes ciliary movement to help expectoration of phlegm easily. It also normalizes sinus secretion and promotes ciliary movement to help discharging pus in chronic sinusitis (empyema).

It is usually used for expectoration of phlegm in acute bronchitis, bronchial asthma, chronic bronchitis, bronchiectasis, pulmonary tuberculosis, pneumoconiosis or postoperative difficulty in expectoration of phlegm. It is also used for discharging pus in chronic sinusitis.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- · If you are pregnant or breastfeeding.
- •If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is<
- to be written by a healthcare professional>>
- •In general, for adults, take 1 tablet (15 mg of the active ingredient) at a time, 3 times a day. The dosage may be adjusted according to your age and symptoms. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include stomach discomfort, nausea, gastric pain, abdominal pain, diarrhea, vomiting, angioedema (edema of face/eyelids/lips), rash, hives, hives-like erythema and itching. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- •rash, respiratory distress, blood pressure reduction [shock, anaphylactoid symptoms]
- •high fever, lip erosion/bloodshot eyes/sore throat, red rash in wide area of skin [mucocutaneous ocular syndrome]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- ullet Keep out of the reach of children. Store away from heat, moisuture and light.
- ·Discard the remainder. Do not store them.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.