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

Internal Revised: 11/2019

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: BEPOTASTINE BESILATE Tablets 10mg "TANABE"

Active ingredient:Bepotastine besilate

Dosage form: white tablet, diameter: 7.1mm, thickness: 3.0mm

Imprint or print on wrapping:(Face) ベポタスチンベシル酸塩「タナベ」10mg,ベポタス

チン,10mg (Back) ベポタスチンベシル酸塩「タナベ」10mg,アレルギ

一性疾患治療剤,Bepotastine Besilate

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Effects of this medicine

This medicine inhibits the internal production and activity of histamines, etc., which cause allergic symptoms, and it thus improves rhinitis symptoms, such as sneezing, running nose, and stuffed nose and itch.

It is usually used to treat allergic rhinitis, hives and itch resulting from skin diseases.

The following patients may need to be careful when 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 or foods. If you have renal dysfunction.
- · 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))
- For adults: In general, take 1 tablet (10 mg of the active ingredient) at a time, twice a day. The dosage may be adjusted according to your age and symptom.
- <u>For children aged 7 years and older</u>: In general, take 1 tablet (10 mg of the active ingredient) at a time, twice a day. In any case, strictly follow the instructions.
- •If you miss a dose, take the dose as soon as possible. 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

- •This medicine may cause drowsiness. Be aware of driving a car or operating dangerous machinery.
- •If you have seasonal allergy, initially take this medicine as instructed shortly before the start of the season and continue until the end of the season.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, dry mouth, nausea, vomiting, gastric pain, diarrhea, gastric discomfort, malaise and hives. 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.

No pertinent entries.

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

- •Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- $\bullet \mbox{Discard}$ the remainder. Do not store them.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.