

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

Internal

Revised: 11/2014

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:Pirenzepine Hydrochloride Tablets 25mg "Nichiiko"

Active ingredient:Pirenzepine hydrochloride hydrate

Dosage form:white to faint yellowish white tablet, diameter: 7.1 mm, thickness: 2.4 mm

Imprint or print on wrapping:ピレンゼピン塩酸塩錠 25mg「日医工」,25mg,n120,ピレンゼピン,NICHI-IKO,Pirenzepine HCl 25mg,「日医工」



Effects of this medicine

This medicine blocks the muscarinic receptor of gastric parietal cells to suppress gastric acid secretion and the same time increases the amount of gastric mucus to enhance the defense function against gastric acid.

It is usually used to improve gastric mucosal lesion (erosion, bleeding and flare, etc.) in acute gastritis and acute exacerbation of chronic gastritis and gastrointestinal symptoms, and treat gastric ulcer and duodenal ulcer.

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 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 (25mg of pirenzepine hydrochloride anhydride) at a time, 3 to 4 times a day. The dosage may be adjusted according to disease, age and symptoms of the patient. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and follow 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 accommodation disturbance (double vision, blurred vision and sensitive to light), etc. Be aware of operating in potentially hazardous activities such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include thirst, constipation, diarrhea, nausea and rash. 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.

- fever, general malaise, sore throat [agranulocytosis]
- rash, hives, breathing difficulty [anaphylactoid symptoms]

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 light, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.