

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

Internal

Revised: 12/2020

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:Atarax-P Capsules 50mg

Active ingredient:Hydroxyzine pamoate

Dosage form:green/white capsule, diameter: 5.3 mm, length: 13.5 mm

Print on wrapping:Atarax-P 50mg, 542, アタラックス-P 50mg



Effects of this medicine

This medicine suppresses an active allergic substance and has a sedative effect by suppressing the central nervous system.

It is usually used to treat hives and itch associated with skin disease. It is also used to treat anxiety/tension/depression associated with neurosis.

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 have: porphyria, convulsive disorders such as epilepsy or its history, QT prolonged, bradycardia or hypokalemia.
- If you are pregnant, possibly 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 the dermatological field: In general, for adults, take 50 to 75 mg of hydroxyzine hydrochloride in 2 to 3 divided doses per day.
In the case of anxiety/tension/depression associated with neurosis: In general, for adults, take 75 to 150 mg of hydroxyzine hydrochloride in 3 to 4 divided doses per day.
In any case, the dosage may be adjusted according to the age or symptoms. This preparation contains 85.22 mg of the active ingredient (50 mg of hydroxyzine hydrochloride) in a capsule. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. 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 drowsiness. Avoid operating dangerous machinery, such as driving a car.
- Drinking alcohol may intensify medicinal or medical effects. Refrain from drinking alcohol while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, malaise, dry mouth, erythema (including exudative or edematous red rash), itch, hives 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.

- respiratory distress, pale face, hives [shock, anaphylaxis]
- palpitation, chest pain, chest discomfort [QT prolonged, ventricular tachycardia (including torsades de pointes)]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- fever, erythema, blister/pustule/erosion [acute generalized exanthematous pustulosis]

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 reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.