

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

Internal

Revised: 04/2017

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: Xyzal Tablets 5mg

**Active ingredient:** Levocetirizine hydrochloride

**Dosage form:** white tablet, major axis: 8 mm, minor axis: 4.5 mm, thickness: 3.2 mm

**Print on wrapping:** (face) ザイザル 5mg

(back) Xyzal 5mg gsk ザイザル 5mg 抗ヒスタミン薬 識別コード: XX



## Effects of this medicine

This medicine exhibits histamine H<sub>1</sub> receptor antagonism and improves symptoms caused by allergy. It is usually used to treat allergic rhinitis, hives, eczema/dermatitis, prurigo and cutaneous pruritus.

## 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 renal disorder or liver disorder.
- If you have convulsive disease such as epilepsy or history of convulsive disease.
- 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 (5 mg of the active ingredient) at a time, once a day, before bedtime. The dosage may be adjusted according to the age or symptoms. However, the maximum daily dose is 2 tablets (10 mg).  
For children: In general, for children 7 or over but under 15 years old, take 1/2 tablet (2.5 mg of the active ingredient) at a time, twice a day, after breakfast and before bedtime.  
In any case, 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 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 sleepiness. Avoid operating dangerous machinery, such as driving a car.
- Please note that alcohol may intensify sleepiness and malaise.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include sleepiness, headache, fatigue, malaise, dry mouth, nausea and dizziness. 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, hypotension, hives [shock, anaphylaxis]
- go into convulsions [convulsion]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- nasal bleeding, gum bleeding, subcutaneous bleeding [thrombocytopenia]

**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.