

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

Internal

Revised: 07/2022

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:ZITHROMAC Tablets 600mg

Active ingredient:Azithromycin hydrate

Dosage form:white tablet, major axis: 19.3 mm, minor axis: 10.5 mm, thickness: 7.0 mm

Imprint or print on wrapping:PFIZER 308



Effects of this medicine

This medicine is a macrolide antibiotic medicine and exerts antibacterial effect by inhibiting proteosynthesis of pathogen.

It is usually used to suppress and treat disseminated mycobacterium avium complex (MAC) associated with acquired immunodeficiency syndrome (AIDS).

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: liver dysfunction or cardiac disease.
If you have previously experienced any symptoms of shock to any medicines (hives, edema, chest distress, facial pallor, cold sweat, breathing difficulty, etc.).
If you or your family member has allergic tendencies such as hives/asthma.
- 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 suppression: In general, for adults, take 2 tablets (1200 mg [titer] of azithromycin) at a time, once a week.
- For treatment: In general, for adults, take 1 tablet (600 mg [titer] of azithromycin) at a time, once a day.
In any case, strictly follow the instructions.
- If you miss a dose and remember it within one week for suppression or within one day for treatment, take the missed dose as soon as possible. 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

- If symptoms suggestive of toxic epidermal necrolysis or oculomucocutaneous syndrome (rash as well as symptoms such as erosion or blister of mucosa [lip, eye, vulva]) occur while or after completion of taking this medicine, discontinue taking this medicine and immediately contact your doctor.
- Since this medicine may cause consciousness disorder, pay close attention to operating dangerous machinery, such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, abdominal pain, nausea, vomiting 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, wheezing (whistling breath), edema of face and lip/swelling in throat [shock, anaphylaxis]
- rash, mucosal erosion/blister, high fever [toxic epidermal necrolysis, oculomucocutaneous syndrome, acute generalized exanthematous pustulosis]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatitis, liver dysfunction, jaundice, liver failure]
- decreased urine output, edema of limbs and face, thirst [acute renal disorder]
- abdominal pain, frequent diarrhea, bloody stool [pseudomembranous colitis, hemorrhagic colitis]

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 at room temperature (1 to 30 degrees Celsius), away from direct sunlight and

moisture.

- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.