

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

Internal

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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: MINEBASE TABLETS 50 FOR PEDIATRIC

Active ingredient: Clarithromycin

Dosage form: white tablet, diameter: 6.1 mm, thickness: approximately 3.3 mm

Print on wrapping: (face) マイネベース錠 50 小児用, 小児用, 50mg, CEO511
(back) MINEBASE・50, マイネベース錠 50 小児用, 50mg, 日局クラリスロマイシン錠



Effects of this medicine

This medicine is a macrolide antibiotic which suppresses bacterial growth by inhibiting protein synthesis of bacteria. It is usually used to treat respiratory infections, otorhinological infections, dermatological infections, and disseminated Mycobacterium avium complex (MAC) disease associated with acquired immunodeficiency syndrome (AIDS).

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 liver dysfunction, renal dysfunction, or cardiac disorder.
- 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 common infections: In general, for children, take 10 to 15 mg (titer) of the active ingredient per kilogram of the body weight a day, in 2 to 3 divided doses. For Legionella pneumonia, take 15 mg (titer) per kilogram of the body weight a day, in 2 to 3 divided doses. The maximum daily dose is 400 mg.
 - For disseminated Mycobacterium avium complex (MAC) disease associated with acquired immunodeficiency syndrome (AIDS): In general, for children, take 15 mg (titer) of the active ingredient per kilogram of the body weight a day, in 2 divided doses.
- This preparation contains 50 mg (titer) of the active ingredient in a tablet. In any case, the dosage may be adjusted according to your disease, age, and symptoms. 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 continue your regular dosing schedule. You should not 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include abdominal pain, diarrhea, rash, nausea, vomiting, taste abnormality, hallucination, disorientation (unable to recognize time, place or name), consciousness disorder, delirium, mania (high tension, tendency to be excited, become active), tremor (trembling of the limbs), numbness, ear ringing, decreased hearing, olfactory abnormality, oral erosion, tooth discoloration, muscle pain, candidiasis (rash, sore, or itch in the external genitalia, stomatitis, difficulty in swallowing or eating), palpitation, and hypoglycemia. 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, facial edema, hives [shock, anaphylaxis]
- palpitation, chest discomfort, chest pain [QT prolongation, ventricular tachycardia, ventricular fibrillation]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [fulminant hepatitis, hepatic dysfunction, jaundice, hepatic failure]
- general malaise, headache, nasal/gum bleeding [thrombocytopenia, pancytopenia, hemolytic anemia, leukocytopenia, agranulocytosis]
- high fever, redness in wide range of skin, bloodshot eyes [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiform]

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.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.