

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

Internal

Revised: 08/2022

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:Dalacin Capsules 75mg

Active ingredient:Clindamycin hydrochloride

Dosage form:opaque orange/opaque pale orange capsule

Imprint or print on wrapping:Dalacin 75mg, UPJOHN 331, **ダラシン** 75mg



Effects of this medicine

This medicine is a lincosamide that has bactericidal action against infectious gram-positive bacteria (e.g. staphylococci, streptococci, pneumococci).

It is usually used to treat various types of infections such as dermal infections, respiratory infections and otolaryngologic infections. Not effective against fungal or virus diseases.

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 weakened.
- If you have: a history of diseases such as colitis, atopic diathesis, esophageal obstruction, myasthenia gravis, renal dysfunction or liver dysfunction.
- 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 2 capsules (150 mg [titer] of the active ingredient) at a time, once every 6 hours. For patients with severe infections, take 4 capsules (300 mg [titer]) at a time, once every 8 hours. In general, for children, take 15 mg (titer) of the active ingredient per kilogram of the body weight daily and for patients with severe infections, take 20 mg (titer) daily, in 3 to 4 divided doses. The dosage may be adjusted according to the age, body weight or symptoms. This preparation contains 75 mg (titer) of the active ingredient in a capsule. Strictly follow the instructions.
- Esophageal retention of this medicine for a long time may cause ulcer with its dissolution. Take it with water or milk and avoid taking immediately before bedtime.
- 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 pseudomembranous colitis, a serious colitis with fulminant diarrhea as a prominent symptom accompanied by fever, abdominal pain, increased white blood cell and mucus/bloody stool in rare cases. If abdominal pain or frequent diarrhea occurs while taking this medicine or in 2 to 3 weeks after completion of this medicine, discontinue taking this medicine and contact your doctor immediately.
- Liver function test is periodically performed since liver dysfunction or jaundice may occur.
- Renal function test is periodically performed since acute renal disorder, azotemia, oliguria or proteinuria may occur.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include itch, rash, edema, stomatitis and candidiasis (sore/itch of external genitalia or mouth). If any of these symptoms occurs, 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.

- breathing difficulty, flush, hives [shock, anaphylaxis]
- abdominal pain, frequent diarrhea with mucus/bloody stool, fever [serious colitis with bloody stool such as pseudomembranous colitis]
- high fever, rash/blister/peeling of skin, stomatitis [toxic epidermal necrolysis, oculomucocutaneous syndrome,

acute generalized exanthematous pustulosis, exfoliative dermatitis]

•fever, rash, lymph node swelling [drug-induced hypersensitivity syndrome]

•dizziness/tinnitus, fever/sore throat, nose/gum bleeding [pancytopenia, agranulocytosis, 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 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.