

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

Internal

Revised: 02/2022

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: Voltaren Tablets 25mg

Active ingredient: Diclofenac sodium

Dosage form: pale yellowish red tablet, diameter: 7.1 mm, thickness: 3.3 mm

Imprint or print on wrapping: ボルタレン 25mg, Voltaren, CG301



Effects of this medicine

This medicine suppresses production of prostaglandin in the body, which is considered as a cause of inflammation/pain/fever. It consequently relieves inflammation/swelling/pain in muscles or joints, and shows antipyretic effects if a fever is present.

It is usually used for the reduction of pain/inflammation such as rheumatoid arthritis, osteoarthritis, low back pain, or for reduction of post-operative and post-tooth extraction pain/inflammation, or for the relief of pain/fever in acute upper respiratory tract inflammation.

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: peptic ulcer, hematological abnormality, renal disorder, hepatic disorder, hypertension, cardiac dysfunction, aspirin-induced asthma or its history, bronchial asthma, influenza or varicella.
- 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))
- For treatment of pain/inflammation: In general, for adults, take 3 or 4 tablets (75 to 100 mg of the active ingredients) a day in 3 divided doses in principle. If you take the medicine on an as-needed basis, take 1 or 2 tablets (25 to 50 mg) at a time.
For treatment of acute upper respiratory tract inflammation: In general, for adults, take 1 or 2 tablets (25 to 50mg of the active ingredients) at a time, as needed. The dosage should be adjusted according to the age or symptoms. However, in principle, the daily dose is limited to 2 times and 4 tablets (100 mg).
In any case, avoid taking the medicine during a fasting state. Strictly follow the instructions.
- Esophageal retention of the medicine for a prolonged period may cause an ulcer with its dissolution. Take it with a large amount of water and avoid taking it just before bedtime.
- If you miss a dose, take one as soon as possible. If it is almost time for the next dose, skip the missed dose and continue 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

- If you experience drowsiness, dizziness, or blurred vision, avoid driving a car or operating dangerous machinery.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include loss of appetite, nausea, vomiting and gastric pain. 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.

- breathing difficulty, impaired consciousness, swelling of the tongue/lips/throat [shock, anaphylaxis]
- nausea, abdominal pain, hematemesis, melena (black stool) [gastrointestinal ulcer accompanied by hemorrhagic shock or intestinal perforation, gastrointestinal stenosis/obstruction]
- fever, rash/blister on the skin, bloodshot eyes, erosion of the lips/mouth [toxic epidermal necrosis, mucocutaneous ocular syndrome, erythroderma]
- decreased urine output, edema, general malaise [acute kidney injury, nephrotic syndromes]
- breathing difficulty, wheezing [severe asthmatic attack (aspirin-induced asthma)]

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 the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store. Ask the pharmacy or medical institution how to discard.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.