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

External

Revised: 11/2015

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 Gel 1%

Active ingredient: Diclofenac sodium

Dosage form: colorless to slightly yellowish gel (jellylike) ointment

Print on wrapping:

Effects of this medicine

This medicine is absorbed through skin, and suppresses production of prostaglandin in the body, which is considered as a cause of inflammation and pain. It consequently relieves inflammation, swelling, and pain in muscles or joints. It is usually used for reduction of pain/inflammation such as osteoarthritis, shoulder periarthritis, muscle pain, low back pain, etc.

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 are a patient with aspirin-induced asthma or its history, bronchial 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>>
- In general, apply an appropriate dose to the affected area in a thin layer evenly, 3 to 4 times a day. Strictly follow the instructions.
- •Do not apply the medicine to mucosal membrane such as eyes or lips. If it reaches the eyes, wash it with water or lukewarm water immediately. Do not apply to the site where the skin is stripped as it may cause smarting or irritation.
- •Do not wrap the applied site with plastic wrap, etc., as it may strengthen the effect.
- •You may notice the applied site get white, however use the medicine as usual.
- •If you miss a dose, apply when you remembered. You should not use two doses at one time.
- ·If you accidentally use more than your prescribed dose, clean off the site thoroughly.
- •Do not stop using this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

• Please note that the medicine may cause softening of synthetic resin, dissolving of paint or tarnishing of metal.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dermatitis (rash, erosion), itch, redness, skin rough and skin irritation. 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.

- •hives, breathlessness, swelling in face/tongue/throat [shock, anaphylaxis]
- •rash/swelling/blister at the applied site [contact dermatitis]

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 keep away from fire as it contains alcohol.
- •Discard the remainder. Do not store them.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.

