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

Internal Revised: 06/2023

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:Hypen Tablets 100mg

Active ingredient: Etodolac

Dosage form:pale yellow tablet, diameter 7.1mm, thickness 3.5mm **Imprint or print on wrapping:**(face) 116 100, (back)ハイペン 100mg



Effects of this medicine

This medicine suppresses prostaglandin formation that causes inflammation, and acts to ease swelling/pain induced by inflammation.

It is usually used to treat inflammation and pain associated with rheumatoid arthritis, osteoarthritis, lumbago, shoulder periarthritis, cervicobrachial syndrome, tendovaginitis. It is also used to reduce pain and inflammation after surgery, and being wounded.

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, abnormality in blood, liver/kidney/heart disorders, hypertension, aspirin-induced asthma (or history of aspirin-induced 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, for adults, take 2 tablets (200 mg of the active ingredient) at a time, twice daily, after meal in the morning and evening. The dosage may be adjusted according to your age and symptoms. Strictly follow the instructions.
- •If you miss a dose, take a dose as soon as possible when you remember. However, 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include abdominal pain, nausea...ecchymosis and cutaneous vasculitis. 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.

- •facial pallor, orthostatic dizziness, decreased conscious [shock]
- •breathing difficulty, lightheadedness, swelling around eyes/lips [anaphylactoid symptoms]
- gastric pain, vomiting, blood vomiting, melena [peptic ulcer]
- •stomatitis, inflamed eyelid/eye, red spots and blisters all over the body [oculomucocutaneous syndrome, toxic epidermal necrosis]
- decreased urination output, swelling, headache [renal failure]

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 unused medicine. Do not store them. If you do not know how to dispose of it, please consult the pharmacy or medical institution where you received it. Please do not give it to others.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.