

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

Internal

Revised: 11/2022

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:Flucam Capsules 13.5mg

Active ingredient:Ampiroxicam

Dosage form:pale yellow/pale yellow capsule, diameter: 5.1 mm, length: 14.2 mm

Imprint or print on wrapping:FLUCAM 13.5mg, F45, フルカム 13.5mg



Effects of this medicine

This medicine inhibits production of prostaglandin (substance that induces inflammation or enhances the pain), and thus relieves joint or muscle pain by suppressing the inflammation and swelling.

It is usually used to relieve inflammation/pain in rheumatoid arthritis, osteoarthritis, low back pain, frozen shoulder and cervico-omo-brachial syndrome.

However, it does not cure the disease itself.

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 disorder, liver dysfunction, renal dysfunction, aspirin asthma or history of it, cardiac function failure, hypertension, bleeding tendency, bronchial asthma, ulcerative colitis, Crohn's disease or infections.
- 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 (27 mg of the active ingredient) at a time, once a day after meal. The dosage may be adjusted according to the age or symptoms. The maximum daily dose is 2 capsules (27 mg). Strictly follow the instructions.
- If you miss a dose, take the missed dose when you notice. However, if you noticed it on and after the next day, skip the missed dose. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist. Lethargy (falling asleep unless stimulated), somnolence (feeling confused due to sleepiness), nausea/vomiting or epigastric pain (pain in the pit of the stomach) may occur.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- If you have a chronic disease (rheumatoid arthritis, osteoarthritis, etc.) and take this medicine for a long period of time, you may undergo urine and/or blood tests on a regular basis. In that case, undergo the tests at the specified date and time.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include pain or discomfort in the stomach/abdomen, rash, itch, eczema, redness, hives, photosensitivity and fixed drug rash. 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.

- abdominal pain, vomiting, vomiting of blood/melena [peptic ulcer, gastrointestinal bleeding]
- dyspnea, generalized hot flush, hives [shock, anaphylaxis]
- high fever, redness of skin, stomatitis [toxic epidermal necrolysis, Stevens-Johnson syndrome]
- decreased urine output, edema, bloody urine [acute renal disorder, nephrotic syndrome]
- symptoms of anemia, bleeding tendency, fever [aplastic anemia, myelosuppression]

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.