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

Internal Revised: 06/2012

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: Myonal Tablets 50mg

Active ingredient: Eperisone hydrochloride

Dosage form:white tablet (ϕ : 7.5 mm, thickness: 4.2 mm) **Imprint or print on wrapping:**ミオナール 50mg, E127



Effects of this medicine

This medicine relaxes increased skeletal muscle tone and dilates blood vessels to increase muscle blood flow. It consequently improves symptoms associated with myotonia, such as stiff shoulder, pain in the neck, headache, low back pain, stiffness of the limbs.

It is usually used to treat cervicobrachial syndrome, shoulder periarthritis, low back pain, spastic paralysis.

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,rach,etc.) to any medicines or foods.
- •If you are a patient with hepatic disorder.
- 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 1 tablet (50 mg of the active ingredient) at a time, 3 times a day after meal. The dosage should be adjusted according to the age or symptoms. Strictly follow the instructions.
- Take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. DO NOT take double doses to make up for the missed dose.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop taking the medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

• The medicine may cause lassitude, light-headedness or drowsiness. Avoid operating dangerous machinery and driving a car, etc.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions, include rash, itch, erythema multiforme exudativum (red and raised rash), drowsiness, nausea/vomiting, loss of appetite, gastric discomfort, abdominal pain, diarrhea, constipation, lassitude, light-headedness, general malaise. 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.

- •rash, urticaria, itching sensation, breathing difficulty [shock, anaphylactoid symptoms]
- •fever, red and flat rash/blister, bloodshot eyes [Steven-Johnson syndrome, toxic epidermal necrosis]

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.
- $\bullet \mbox{Discard}$ the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.