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

Internal

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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:DULOXETINE CAPSULES 30mg「OHARA」[pain associated with each disease]

Active ingredient: Duloxetine hydrochloride

Dosage form:pale yellowish white/faintly yellowish white and opaque capsule, major axis: 15.8 mm, minor axis: 5.8 mm

Print on wrapping:デュロキセチン 30mg「オーハラ」、デュロキセチン、30、Duloxetine30mg「OHARA」、デュロキセチン「オーハラ」、30mg

Effects of this medicine

This medicine acts on an inhibitory pathway of pain in central nervous system and inhibits the reuptake of serotonin and noradrenaline, thereby exhibiting analgesic effects.

It is usually used to treat pain associated with diabetic neuropathy, fibromyalgia, chronic low back pain and osteoarthritis.

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 have liver disorder, renal disorder or narrow-angle glaucoma.
・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))

・For pain associated with diabetic neuropathy : In general, for adults, start with taking 20 mg of duloxetine once a day after breakfast. After taking 20 mg for one week or more, the dosage is increased to 40 mg a day. According to the symptoms, the dosage may be increased up to 60 mg a day when this medicine exhibits an insufficient effectiveness after taking 40 mg for one week or more.

For pain associated with fibromyalgia, chronic low back pain and osteoarthritis : In general, for adults, start with taking 20 mg of duloxetine once a day after breakfast. After taking 20 mg for one week or more, the dosage is increased to 40 mg a day. Furthermore, after taking 40 mg for one week or more, the dosage is increased to 60 mg a day.

This preparation contains 30 mg of duloxetine in a capsule. Strictly follow the instructions.

・If you miss a dose, take the missed dose as soon as you remember. However, if it is almost time for the next dose, 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.
・Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

・Pay close attention when driving a car or operating dangerous machinery because this medicine may cause drowsiness or dizziness. If you become aware of these symptoms, avoid driving a car or operating dangerous machinery.
・Drinking alcohol may intensify the effects or the adverse drug reactions of this medicine.
・Pay attention to the foods containing hypericum perforatum (St. John's wort) because they may enhance the action of serotonin.
・The following symptoms may appear: anxiety, irritability, impatience, excitability, panic attacks, insomnia, disturbance of mood or physical conditions by slight stimulations, hostility, aggression, impulsive behavior, restlessness, continued abnormally growing elation. You may have symptoms such as suicidal ideation, suicide attempt. If any of these symptoms are observed, consult with your doctor.
・For the elderly, pay attention to falls because they may be caused by dizziness.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, somnolence, dry mouth, headache, constipation, diarrhea, dizziness, abdominal pain, insomnia, malaise, decreased appetite, vomiting, increased body weight, abdominal discomfort, rash, itch, hives, contact dermatitis, photosensitivity (excessive sunburn caused by

sunlight, itch, pigmentation), angioedema and skin 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.

- anxiety, excitation, sweating [serotonin syndrome]
- muscle stiffness, rapid pulse, fever [malignant syndrome]
- increased body weight without edema over a short period, convulsion, consciousness disturbance [syndrome of inappropriate antidiuretic hormone secretion (SIADH)]
- malaise, loss of appetite, yellowing of skin or the white of eyes [liver dysfunction, hepatitis, jaundice]
- high fever, blister, erosion in mucous membrane of eyes or mouth [mucocutaneous ocular syndrome]

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 the reach of children. Store at a room temperature away from direct sunlight and moisture.
- Discard the remainder. Do not store them. Consult the pharmacy or the medical institution on how to discard them.
- [To family members] If patients show behavioral changes such as suicidal ideation and aggression, or aggravation of depression or depressive states, keep in close contact with your doctor.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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