

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

Internal

Revised: 12/2007

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:EBRANTIL Capsules 30mg

Active ingredient:Urapidil

Dosage form:capsule, minor axis: 5.3mm, major axis: 14.6mm

Imprint or print on wrapping:EBRANTILCap.30mg, エブランチルカプセル 30mg, KC154, 30mg



Effects of this medicine

This medicine dilates peripheral vessels and lowers blood pressure by its antagonistic action on α_1 receptors. Also, it makes urinating easier by suppressing smooth muscle contraction in the prostate and the urethra, and dilating the urethra.

It is usually used to treat hypertension, and dysuria associated with prostatic hyperplasia and neurogenic bladder.

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 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 the treatment of essential hypertension, renal hypertension, hypertension associated with pheochromocytoma:

In general, for adults, the initial dose is started with 15 mg of the active ingredient at a time, twice daily, and if the effect is insufficient, the dose will be gradually increased up to 60 mg at a time, twice daily, after breakfast and supper, at intervals of 1 to 2 weeks. The dosage may be adjusted according to your age or symptoms. Strictly follow the instructions.

For the treatment of dysuria associated with prostatic hyperplasia: In general, for adults, the initial dose is started with 15 mg of the active ingredient at a time, twice daily, and if the effect is insufficient, the dose will be gradually increased up to 30 to 45 mg at a time, twice daily, after breakfast and supper, at intervals of 1 to 2 weeks. The dosage may be adjusted according to your age or symptoms, however, the maximum daily dosage is 90 mg. Strictly follow the instructions.

For the treatment of dysuria associated with neurogenic bladder: In general, for adults, the initial dose is started with 15 mg of the active ingredient at a time, twice daily, and if the effect is insufficient, the dose will be gradually increased up to 30 mg at a time, twice a day, after breakfast and supper, at intervals of 1 to 2 weeks. The dosage may be adjusted according to your age or symptoms, however, the maximum daily dosage is 90 mg. Strictly follow the instructions.

- If you miss a dose, take a dose as soon as you remember. However, take an interval of 4 to 5 hours before the next dose. If it is 2 to 3 hours or less before 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

- You may feel dizziness/stagger due to decreased blood pressure. Pay close attention to driving a car, working at heights, or operating dangerous machinery while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, headache dull, dizziness, nausea, vomiting, lightheadedness, stagger and 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.

- general malaise, loss of appetite, nausea, vomiting [liver dysfunction]

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 away from direct sunlight, heat and moisture.

•Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.