

# 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:EC-Doparl Combination Tablets

**Active ingredient:**Levodopa

Benserazide hydrochloride

**Dosage form:**pale red tablet, diameter: 9.1 mm, thickness: 3.5 mm

**Imprint or print on wrapping:**KH 108,イーシー・ドパール配合錠,EC-Doparl



## Effects of this medicine

The active ingredient of this medicine, levodopa, is transferred to the brain after being absorbed and is converted into dopamine. Benserazide hydrochloride increases blood levodopa concentration and enhances the transfer of levodopa to the brain.

Dopamine deficiency in the brain induces Parkinsonian symptoms such as trembling limbs and mouth, muscle stiffness, difficulty in walking and amimia.

It supplements deficient dopamine in the brain, and is usually used in the treatment of Parkinson's disease and Parkinsonian syndrome.

## 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 angle-closure 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 patients who are untreated with levodopa: In general, for adults, take 1 to 3 tablets a day as the initial dose at one time or in 2 or 3 divided doses, after meal. The dosage will be increased by 1 or 2 tablets a day every 2 or 3 days, and then take 3 to 6 tablets a day as the maintenance dose.  
For patients who are treated with levodopa: In general, for adults, take the equivalent of approx. 1/5 levodopa dose that you are taking (this preparation contains 100 mg of levodopa in a tablet) a day as the initial dose at one time or in 2 or 3 divided doses, after meal. The dosage will be increased or decreased gradually, and then take 3 to 6 tablets a day as the maintenance dose.  
The dosage may be adjusted according to the age or symptoms in any case. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. 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

- This medicine may cause sudden onset of sleep, somnolence (falling into a half-doze) and decline in attention and reflex movement without any signs. Avoid driving a car or engaging in dangerous activities.
- In a very rare case, saliva, sputum, oral mucosa, sweat, urine and stool may turn black.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include involuntary movements (face, mouth, neck and limbs, etc.), nausea and hallucination. 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.**

- high fever, stiffness of the body, trembling limbs [neuroleptic malignant syndrome]
- feeling as if something that actually does not exist exists, depressed mood/decline of thinking ability, inconsistent behavior [hallucination, depression, confusion]
- prolonged bleeding, general dullness, yellowing of the skin and the white of eyes [hemolytic anemia, thrombocytopenia]

- sudden intolerable drowsiness [sudden onset of sleep]
- headache, eye pain, reduced visual acuity [angle-closure glaucoma]

**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 light, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.
- [To family members] Despite an unfavorable social outcome, the following symptoms may appear: repeated gambling, repeated excessive unplanned shopping, and an abnormal rise in sexual desire and appetite, etc. If any of these symptoms are observed, consult with your doctor.

**For healthcare professional use only**      /      /

For further information, talk to your doctor or pharmacist.

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