

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: NEODOPASTON COMBINATION TABLETS L250

Active ingredient: Levodopa
Carbidopa

Dosage form: light red oval tablet,
major axis: 14.8 mm, minor axis: 8.2 mm, thickness: 4.2 mm

Print on wrapping: ネオドパストン配合 L250、ネオドパストン、配合 L250、
Neodopaston L250



Effects of this medicine

This medicine is a combination preparation of levodopa and carbidopa. Levodopa changes into dopamine in brain to supplement insufficient dopamine and consequently improves the symptoms of Parkinson's disease. Carbidopa enhances the transfer of levodopa into brain.

It is usually used to treat Parkinson's disease and parkinsonian syndrome.

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 glaucoma, liver/renal disorder, diabetes mellitus, heart/lung disease, bronchial asthma and psychiatric symptoms such as suicidal tendency.
- 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 have never taken levodopa before : In general, for adults, the initial dose is started at 100 to 125 mg of levodopa at a time, 100 to 300 mg a day, and the dosage is increased by 100 to 125 mg every day or every other day, then the optimal dose is determined as the maintenance dose (standard dose is 200 to 250 mg of levodopa at a time, 3 times a day). The dosage may be adjusted according to the symptoms. However, the maximum daily dose should not exceed 1,500 mg a day.
For patients who have been taking levodopa : In general, for adults, at an at least 8-hour interval after taking levodopa alone, the initial dose is determined based on equivalent to one fifth of levodopa of the daily maintenance dose, and take it in 3 divided doses a day. Thereafter, the dosage may be adjusted according to the symptoms, and the optimal dose is determined as the maintenance dose (standard dose is 200 to 250 mg of levodopa at a time, 3 times a day). The maximum daily dose should not exceed 1,500 mg a day.
This preparation contains 250 mg of levodopa in a tablet. Strictly follow the instructions.
- If you miss a dose, take the missed dose when you remember. 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 sleep, decreased consciousness, decreased attention/concentration/reflection. Avoid operating dangerous machinery such as driving a car.
- Your sweat, urine and saliva may turn black. In that case, consult with your doctor or pharmacist.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, loss of appetite, vomiting, involuntary movement (tremor, continuous involuntary movements of tongue or jaw), insomnia, orthostatic hypotension (dizziness on standing up), rash and anemia. 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, muscle rigidity, tremor or convulsion of limbs [malignant syndrome]

- unable to tell the time/place, seeing things or hearing sounds that do not exist, general malaise [confusion, hallucination, depression]
- epigastric pain, tenderness in upper abdomen, vomiting [deterioration of gastric or duodenal ulcer]
- light-headedness, yellowing of skin/the white of eyes, fatiguability [hemolytic anemia, decreased platelets]
- sudden drowsiness [sudden sleep]
- severe eye pain, headache, sudden decrease of 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 direct sunlight, heat (including inside the car etc.) and moisture.
- Discard the remainder. Do not store them.
- [To the family members] Despite the resulting social disadvantage, the following uncontrollable impulsive symptoms may appear: repetitive gambling, repetitive excessive unplanned shopping, a pathological increase in sexual desire or appetite. You and your family members should be informed of these symptoms by your doctor until you fully understand them. If any of these symptoms occur, consult with your doctor.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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