

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

Self-injection

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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:Apokyn subcutaneous injection 30mg

Active ingredient:Apomorphine hydrochloride hydrate

Dosage form:colorless to light yellowish green or light yellowish red limpid injectable solution (cartridge)

Imprint or print on wrapping:



Effects of this medicine

This medicine acts on the receptors of dopamine which is a neurotransmitter in the brain, and improves parkinsonian symptoms such as trembling, muscle stiffness, slow movement and abnormal posture.

It is usually used to improve off symptoms (experiencing some symptoms when the medication stops working before the next dose) in Parkinson's disease. It is only used in the patients who cannot obtain sufficient efficacy even after receiving frequent treatments with other antiparkinsonian drugs or dose increase.

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: liver dysfunction or long QT syndrome.
- If you have cardiovascular disorder or a history of it.
- If you have a history of arrhythmia.
- 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, inject subcutaneously using a dedicated injector when you have any off symptoms. For adults, start with 1 mg of apomorphine hydrochloride at a time and increase by 1 mg per dose under monitoring the condition, and then the maintenance dose (a dose of 1 to 6 mg) will be determined. The dosage may be adjusted according to the symptoms, however, a single dose is restricted to maximum of 6 mg. Strictly follow the instructions.
- You should take an interval of at least 2 hours to use a next dose. The maximum dose frequency per day is restricted to 5 times.
- You should rotate the injection sites, including upper arm, thigh and abdomen, according to the instructions of your doctor every time you inject this medicine. Avoid injecting in the same site in a short term.
- You should never reuse a needle which was already used.
- You should never share the injector and cartridge with other people.
- If you accidentally used more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop using this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause sudden onset of sleep and somnolence (falling into a half-dose) without any signs. Do not engage in dangerous activities, such as driving a car, operating machinery or working at heights.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, changes in injection sites (lump, hematoma and itching), dyskinesia (involuntary persisting movement of the mouth), yawning, somnolence and visual hallucination (seeing things that do not actually exist). 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.

- sudden intolerable drowsiness, falling asleep unless stimulated [sudden onset of sleep, somnolence]
- palpitations, fainting [QT prolongation, fainting]
- cold sweat, chest constrictive pain, chest oppressive feeling [angina pectoris]
- dizziness, light headedness, dizziness on standing up [decreased blood pressure, orthostatic hypotension]
- seeing things or hearing sound that do/does not actually exist, feeling as if something that actually does not exist exists, baseless and improbable thoughts [visual hallucination, hallucination, auditory hallucination, delusions]

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. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give this medicine to anyone else.
- Use up all of this medicine within 14 days after starting to use it.
- [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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