

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: Cialis Tablets 20mg

Active ingredient: Tadalafil

Dosage form: gray-yellow tablet, major axis: approx. 12.3 mm, minor axis: approx. 7.6 mm, thickness: approx. 5.0 mm

Print on wrapping: Cialis 20mg, シアリス 20, シアリス 20mg, ニトログリセリンなどの硝酸薬と本剤は併用できません



Effects of this medicine

This medicine increases cGMP in corpus spongiosum by inhibiting PDE-5 enzyme. It consequently relaxes smooth muscle, increases blood flow into penile tissue to cause an erection. Erection doesn't occur without sexual stimulation.

It is usually used to treat erectile dysfunction (inability to get or keep an erection enough with sexual activity). It does not increase sexual desire, or prevent the spread of sexually transmitted diseases.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.
If you are a patient with cardiovascular disorder, unstable angina, arrhythmia, hypotension, hypertension, hepatic disorder, retinitis pigmentosa.
If you have a history of angina during sexual activity.
If you have a history of myocardial infarction in these 3 months.
If you have a history of cerebral infarction/intracranial hemorrhage in these 6 months.
- 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 >>
- General dosage regimen:
In the usual case, for adults, take 10 mg of the active ingredient at a time, once a day about 1 hour before sexual activity. If the effect is insufficient and tolerated, the dose may be increased to 20 mg at a time. Take the next dose at least 24 hours apart.
If you have mild-to-moderate hepatic disorder, for adult, take 10 mg of the active ingredient at a time, once a day about 1 hour before sexual activity. This is the maximum dose. Take the next dose at least 24 hours apart.
If you have moderate renal disorder, for adults, start with taking 5 mg of the active ingredient at a time, once a day about 1 hour before sexual activity. Take the next dose at least 24 hours apart. The dose may be increased to 10 mg, but it is the maximum dose. Take the next dose at least 48 hours apart.
If you have severe renal disorder, for adults, take 5 mg of the active ingredient at a time, once a day about 1 hour before sexual activity. This is the maximum dose. Take the next dose at least 24 hours apart.
1 tablet contains 20 mg of the active ingredient. In any case, strictly follow the instructions of your doctor/pharmacist.
- DO NOT take double doses.
- If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.

Precautions while taking this medicine

- The medicine may cause dizziness or vision disorder such as blurred vision. Be careful when working at heights, driving a car, or operating dangerous machinery.
- Avoid drinking grapefruit juice, as it may intensify the effects and side effects of the medicine.

Possible adverse reactions to this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: headache, hot flush, glow, indigestion, back pain, muscle pain, nasal obstruction, pain in limbs, etc.

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.

- rash, swelling in face, erosion in lips/mouth/conjunctiva [hypersensitivity]

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 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.