



Cialis®

Pharmacist's Intervention
Required Medicine (PIRM)

[Therapeutic drug for erectile dysfunction]

Brand name: Cialis®

- This drug is a treatment for men with erectile dysfunction. Erectile dysfunction is a condition in which a man cannot achieve or maintain sufficient hardness to have satisfactory sexual activity.
- Tadalafil, the active ingredient, relaxes blood vessels in the penis and increases blood flow to the penis.
- Taking this drug alone does not cause erection. An erection occurs only when you are sexually stimulated. The effect appears from about 30 minutes after taking this drug and is observed up to 36 hours after taking this drug.
- It can be taken with or without food.
- This drug is not effective in preventing sexually transmitted diseases.

Precautions



When not to use the product

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions/incidents are more likely to occur.)

❶ **This product should not be taken in the following persons.**

- (1) Patients who have had an allergic symptom to this drug or its ingredients
- (2) Patients who are using nitrates, etc. such as nitroglycerin (Millisrol, etc.), amyl nitrite, isosorbide dinitrate (Nitorol, Frandol, etc.), and Nicorandil (Sigmart, etc.) which are often used for heart diseases such as angina pectoris (Please check the drugs you are using carefully.)
- (3) Patients who are using riociguat (Adempas, etc.), ketoconazole (oral drug, not marketed in Japan), itraconazole (Itrazole, etc.), clarithromycin (Clarith, Klaricid, etc.) (Please check the drugs you are using carefully.)
- (4) Patients who are considered inappropriate for sexual activity because of cardiovascular disorders, etc.
- (5) Patients who have unstable angina or have had angina pectoris during sexual activity.
- (6) Patients whose irregular heartbeat has not been suppressed by taking drugs, patients with hypotension (blood pressure < 90/50 mmHg), or patients with high blood pressure despite taking drugs that lower blood pressure (resting blood pressure > 170/100 mmHg)
- (7) Patients who have experienced myocardial infarction within the past 3 months
- (8) Patients who have experienced cerebral infarction/cerebral hemorrhage within the past 6 months
- (9) Patients who have been diagnosed with liver abnormalities by a physician
- (10) Patients who have been diagnosed with kidney abnormalities by a physician
- (11) Persons diagnosed as having the following: Retinal pigment degeneration
- (12) Women

(Sexual activity is associated with a risk to the heart. If you are suspected to have a cardiovascular disorder, you should check with a physician in advance. Myocardial infarction, etc. may occur.)

❷ **Please refrain from taking grapefruit juice, etc., which affect this drug.**



Consultation

❶ **The following persons should contact a physician or pharmacist for a consultation before administration.**

- (1) Patients undergoing medical treatment or receiving medication from a physician, or patients who are taking the following drugs: Therapeutic drugs for benign prostatic hyperplasia or drugs to lower blood pressure [α -blockers (doxazosin, etc.), amlodipine, etc.], anti-HIV drugs (ritonavir, saquinavir, etc.), antimicrobial drugs (rifampicin, etc.), antiepileptic drugs (phenytoin, phenobarbital, etc.)
- (2) The elderly
- (3) Patients who have experienced allergic symptoms associated with drugs, etc.
- (4) Persons diagnosed as having the following: Priapism (persistent erection for 4 hours or longer), blood disorder (sickle cell anemia, multiple myeloma, leukemia, etc.), bleeding disorder, peptic ulcer, deformation of the penis (flexion, penile fibrosis, Peyronie's disease, etc.)
- (5) Patients undergoing other medical treatment for erectile dysfunction
- (6) Persons who experience severe difficulty breathing or chest pain during light or moderate exercise (for example, walking fast for about 20 minutes, running up one floor of stairs with quick steps, etc.)

❷ **If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician or pharmacist for a consultation.**

Related sites	Symptoms
Skin	Rash/redness, itching, heavy sweating, inflammation around nails
Gastrointestinal system	Nausea/vomiting, indigestion, heartburn, diarrhea, dry mouth, gastritis, abdominal pain, feeling of discomfort in the stomach, constipation, abdominal distension, soft stool, difficulty in swallowing, and sour taste in the throat
Neuropsychiatric system	Headache, dizziness, sleep disorder, tingling sensation, sleepiness, anxiety, migraine, reduced sensibility
Sensory organ	Blurred vision, eye pain, watery eyes, abnormal sensation in the eye, congestion of the eye, eye discharge, ear ringing, visual disturbance, swelling of eyelids
Cardiovascular system	Palpitations, hot flush, chest pain, faster pulse, syncope, hypertension, hypotension, cold sweat, decrease in consciousness, difficulty in moving unilateral extremities, and difficulty in speech

(Continued from the front)

Related sites	Symptoms
Respiratory system	Difficulty in breathing, nasal congestion, rhinitis, vomiting of blood associated with cough, nosebleeds, swollen throat
Urinary system	Urination difficulty, erection increased, abnormal erection or its persistence
Other	Fatigue, malaise, hot sensation, oedema, mucosal edema, pain, back pain, muscle pain, joint pain, neck pain, buttock pain, muscle twitching, musculoskeletal stiffness, weight increased

The following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid:

Name of symptom	Symptoms
Hypersensitivity	Rash, urticaria, swollen face
Exfoliative dermatitis	Redness of the skin on almost the whole body, dandruff- or scab-like accretions peel off, often accompanied with fever
Oculomucocutaneous syndrome (Stevens-Johnson syndrome)	Hyperthermia, ocular hyperemia, eye discharge, lip erosion, sore throat, widespread skin rash/redness, etc. may persist or suddenly worsen.

- ❶ If sudden deterioration of vision or loss of vision occurs after taking this drug, discontinue the use of it, and immediately seek an ophthalmologist for medical treatment.
- ❷ Erection may persist for 4 hours or longer after taking this drug. If erection persists for 6 hours or longer, delay in treatment may result in loss of erectile function. Immediately seek medical aid if erection persists for more than 4 hours.
- ❸ If no effects are obtained after taking this drug 4 to 8 times, consult a physician or pharmacist, being sure to take this leaflet with you. (Erectile dysfunction may be related to diseases such as heart disease, hypertension, and diabetes mellitus. Consult a physician or pharmacist as soon as possible.)
- ❹ After taking this drug, attention should be paid when working at high places, driving vehicles or operating machines (Symptoms such as dizziness and blurred vision may occur.)

Indication

Erectile dysfunction

(Persons who cannot achieve or maintain sufficient erection to have satisfactory sexual activity)

<Precautions related to indications>

(1) This drug is not an aphrodisiac or libido enhancer. (2) This drug is not effective in preventing sexually transmitted diseases. (3) Taking this drug alone does not cause erection. An erection occurs only when you are sexually stimulated. The effect appears from about 30 minutes after taking this drug and lasts up to 36 hours after taking this drug.

Dosage and administration

Adult men (aged 18 years or older) Take 1 tablet at a time with cold or lukewarm water about 1 hour before sexual activity. Do not take this drug more than one tablet per day. Take this medicine in intervals of at least 24 hours.

<Precautions of Dosage and Administration>

- (1) Follow the dosage and administration strictly.
- (2) It can be taken before or after meals.
- (3) Avoid taking this drug in the event of excessive alcohol consumption.
- (4) Continuous daily dosing is not recommended. Consult a physician if you take this medicine every day.
- (5) How to take out the medicine: As indicated in the figure on the right, strongly press the convex part of the PTP sheet with your finger tip to break the aluminum foil on the back side and take out the medicine. (If you swallow the PTP sheet by mistake, its sharp edges may perforate your esophageal mucosa, etc., resulting in unexpected accidents.)



(Figure showing how to take out the medicine from the PTP sheet)

Ingredients

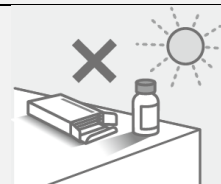
Tadalafil 10 mg

Per tablet

Additives: Cross CMC-Na, cellulose, lactose, hydroxypropylcellulose, hypromellose, magnesium stearate, talc, titanium oxide, ferric oxide, triacetin, sodium lauryl sulfate

Precautions for storage and handling

- (1) Store in a cool, low humidity place away from direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer the medicine to a different container. (It may lead to misuse or alter the quality of the drug.)
- (4) Do not take this medicine after the expiration date.



Contact information

Please contact the store where you bought the product or the customer service office.

Customer Service Office, SSP Co., Ltd. Phone 0120-028-193 Business hours: 9:00 to 17:00 (excluding Saturdays, Sundays, and holidays)

Manufactured and
Distributed by:

50



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