

Informational Materials for Users



for the treatment of erectile dysfunction (ED)

Pharmacist's Intervention Required Medicine (PIRM)

Active ingredient: tadalafil

Strength: 10 mg per tablet

Important Information

- ▶ This product does not increase sexual desire. Taking this product alone will not cause an erection. An erection will only happen with sexual stimulation.
- ▶ Do not take this product if you take nitrate medicines (for example, nitroglycerin), which are commonly used to treat heart conditions such as angina. Serious side effects may occur.
- ▶ Sexual activity requires the consent and respect of both people. **Sexual activity without the other person's consent is a criminal offense.**
- ▶ This product does not protect against sexually transmitted infections. To prevent sexually transmitted infections, take other appropriate protective measures, such as using condoms.
- ▶ Take this product as directed. Never increase the amount you take without discussing with your healthcare provider. Taking too much may cause side effects (including headache, back pain, indigestion, skin redness, and muscle pain). Never take more than one dose in a 24-hour period. Wait at least 24 hours before taking your next dose.
- ▶ Never give this product you purchased to anyone else. This could be very dangerous because the other person may have a heart condition that makes sexual activity unsafe or may be taking medicines that should not be taken with this product.

This document has been prepared to help you understand how to use this product properly and the risks associated with its use. It explains what you should know about taking this product in plain language, based on the package insert. When you purchase this product, you will be assisted by a pharmacist who has completed training on this product. If you have any questions, please ask your pharmacist.

*This document is an English translation of informational materials for a medicine approved in Japan. It is provided for reference purposes only.

SSP Co., Ltd.



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What is erectile dysfunction (ED)?

ED is when a man is consistently or repeatedly unable to get or keep an erection firm enough for satisfactory sexual activity.

A survey conducted by SSP Co., Ltd. found that about 1 in 2 people* in Japan may have ED. ED is not uncommon. It can happen to anyone and is nothing to be ashamed of.

ED may be a sign of an underlying medical condition (for example, heart or vascular disease). However, ED itself often improves with proper treatment.

*Participants with an Erection Hardness Score (EHS) of Grade 3 or lower were considered likely to have ED.

Survey details

Title: Survey on ED and sexual well-being
Conducted by: NEO Marketing Inc.
Survey period (Japan): December 19 to December 23, 2025
Survey period (outside Japan): January 14 to January 22, 2026
Participants: A total of 5,000 men and women aged 20 to 69 years in Japan (4,000 men and 1,000 women) and a total of 5,000 men and women aged 20 to 69 years in five other countries (United States, Italy, Sweden, South Korea, and Thailand; 800 men and 200 women from each country)

ED is one of the most common chronic conditions, affecting more than 100 million men worldwide.

Causes of ED

Many things can cause or contribute to ED, including risk factors, underlying medical conditions, and certain medicines.

- **Body changes:** Blood flow, nerve function, and hormone balance can affect the ability to get an erection.
- **Emotional factors:** Anxiety, stress, and relationship problems can also play a role.
- **Lifestyle habits and medical conditions:** Diabetes, high blood pressure, smoking, and drinking too much alcohol can also contribute to ED.

Potential risk factors for ED	Underlying medical conditions that increase the risk of ED	Medicines that may affect the ability to get an erection
•Aging •Lack of exercise •Obesity •Smoking and others	• Heart or vascular disease • High blood pressure • Diabetes • Psychological factors and mental health conditions • Low testosterone • Chronic kidney disease • Lower urinary tract symptoms • Neurological disorders • Injury or surgery • Sleep apnea syndrome and others	• Medicines that lower blood pressure • Medicines to treat an enlarged prostate • Nonsteroidal anti-inflammatory drugs (NSAIDs) • Antidepressants and others

What are the ingredients in this product?

Amount of tadalafil per tablet 10 mg

Inactive ingredients: croscarmellose sodium, cellulose, lactose, hydroxypropyl cellulose, hypromellose, magnesium stearate, talc, titanium dioxide, ferric oxide, triacetin, and sodium lauryl sulfate

Who can take this product

This product is for adult men (18 years of age or older) with ED who are unable to get or keep an erection firm enough for satisfactory sexual activity. Women should not take this product.

The active ingredient, tadalafil, relaxes the blood vessels in the penis and increases blood flow to the penis. Taking this product alone will not cause an erection. An erection will only happen with sexual stimulation.

Please use the **check sheet** to make sure Cialis® is right for you. Sexual activity itself can increase the risk of heart problems. If you may have a heart or vascular condition, be sure to talk to your doctor before taking this product. It may increase the risk of a heart attack or other heart problems.

Is this product right for me?

1. What medicines are you currently taking?

Carefully review the medicines you are currently taking. Do not take this product if you:

- (1) have ever had an allergic reaction to this product or any of its ingredients
- (2) are taking any medicines called nitrates commonly used to treat heart conditions such as angina, including: nitroglycerin (such as Millisrol), amyl nitrite (including recreational drugs known as "poppers"), isosorbide dinitrate (such as Nitorol or Frandol), or Nicorandil (such as Sigmart)
- (3) are taking: riociguat (such as Adempas), ketoconazole (oral form; not sold in Japan), itraconazole (such as Itrazole), or clarithromycin (such as Clarith or Klaricid)

2. Do you have any of these medical conditions?

Carefully check whether any of the following apply to you. Do not take this product if you:

- (1) have a heart/vascular condition or other health condition that makes sexual activity unsafe
- (2) have unstable angina or have experienced angina during sexual activity
- (3) have irregular heartbeats that are not controlled with medicine, have low blood pressure (below 90/50 mmHg), or have high blood pressure not controlled with medicine (resting blood pressure above 170/100 mmHg)
- (4) have had a heart attack within the past 3 months
- (5) have had a stroke or bleeding in the brain within the past 6 months
- (6) have been told by your doctor that you have a liver problem
- (7) have been told by your doctor that you have a kidney problem
- (8) have been diagnosed with retinitis pigmentosa

3. Talk to your doctor or pharmacist before taking this product if you:

(1) are being treated by a doctor, are taking prescription medicines, or are taking any of the following medicines: medicines used to treat an enlarged prostate or to reduce blood pressure (including alpha blockers such as doxazosin, or amlodipine), medicines used to treat HIV (such as ritonavir or saquinavir), antibiotics (such as rifampicin), or medicines used to treat epilepsy (such as phenytoin or phenobarbital)
(2) are of an advanced age (65 years or older)
(3) have ever had an allergic reaction to a medicine or other substance
(4) have been diagnosed with any of the following: priapism (an erection that lasts for more than 4 hours), a blood disorder (such as sickle cell anemia, multiple myeloma, or leukemia), a bleeding disorder, a stomach ulcer, or a deformed penis shape (such as curvature, penile fibrosis, or Peyronie's disease)
(5) are receiving any other treatment for ED
(6) become very short of breath or have chest pain during light or moderate physical activity (for example, walking briskly for about 20 minutes or quickly climbing one flight of stairs)

Indications

Erectile dysfunction

(someone who is unable to get or keep an erection firm enough for satisfactory sexual activity)

How to take this product

- Adult men (18 years of age or older) with ED should take **1 tablet** with water or lukewarm water about 1 hour before sexual activity.
- This product is not affected by food or alcohol, so it can be taken on an empty stomach, before or after meals, **without regard to meal timing.**

What should I know when taking this product?

1. Important precautions

- **Always wait at least 24 hours before taking your next dose.**
- Do not consume grapefruit juice, grapefruit, or foods made with large amounts of grapefruit juice or peel for at least 48 hours before and 48 hours after taking this product.
- Avoid taking this product with a large amount of alcohol, as this may temporarily reduce your ability to get an erection. Dizziness and a drop in blood pressure when standing up have also been reported.
- Taking this product every day for several days in a row is not recommended. If you plan to take this product for several days in a row, talk to your doctor.
- Always take this product exactly as directed.
- How to remove a tablet:
As shown in the illustration on the right, push firmly on the raised side of the blister pack with your fingertip to break the aluminum foil on the back and remove the tablet before taking it. (Accidentally swallowing the tablet still inside the blister pack may result in serious injury, such as the blister piercing the lining of the esophagus.)



(illustration showing how to remove tablet from blister pack)

2. How this product works

- This product starts to work about 30 minutes after you take it.
- The effects may last for **up to 36 hours** (1.5 days). This does not mean you will have an erection the entire time. An erection will only happen with sexual stimulation.

3. If this product is not working

- If you have taken this product 4 to 8 times and have not noticed any effect, talk to your doctor or bring the package insert and talk to your pharmacist. Your ED may be related to a medical condition such as heart disease, high blood pressure, or diabetes.

4. Things to watch for after taking this product

- If you experience any of the following symptoms after taking this product, they may be side effects. Stop taking this product immediately and talk to your doctor or pharmacist, bringing the package insert with you.

Affected area	Symptoms
Skin	Rash/redness, itching, excessive sweating, inflammation around the nails
Digestive system	Nausea/vomiting, indigestion, heartburn, diarrhea, dry mouth, gastritis, stomach pain, stomach discomfort, constipation, bloating, loose stools, difficulty swallowing, acid reflux
Nervous system and mental health	Headache, dizziness, sleep problems, tingling sensation, drowsiness, anxiety, migraine, reduced sensation
Sensory organs (such as eyes and ears)	Blurred vision, eye pain, watery eyes, unusual sensation in the eyes, red eyes, eye discharge, ringing in the ears, vision problems, swollen eyelids
Cardiovascular system	Palpitations, hot flashes, chest pain, fast heartbeat, fainting, high blood pressure, low blood pressure, cold sweats, decreased consciousness, difficulty moving the hand or foot on one side of the body, difficulty speaking
Respiratory system	Difficulty breathing, congested nose, rhinitis, coughing up blood, nosebleeds, swelling of the throat
Urinary system	Difficulty urinating, stronger erections, abnormal or prolonged erections
Other	Fatigue, tiredness, feeling hot, swelling, swelling of the mucous membranes, pain, back pain, muscle pain, joint pain, neck pain, buttock pain, muscle cramps, muscle and joint stiffness, weight gain

- In rare cases, the following serious symptoms may occur. If this happens, see a doctor right away.

Condition	Symptoms
Hypersensitivity reactions	Rash, hives, swelling of the face
Exfoliative dermatitis	Skin redness over most of the body, with scaling or crusting that peels off, often with a fever
Mucocutaneous ocular syndrome (Stevens-Johnson syndrome)	High fever, red eyes, eye discharge, sores on the lips, sore throat, widespread rash or redness that persists or rapidly gets worse

- If you notice a sudden decrease or loss of vision after taking this product, stop taking it and see an eye doctor right away.
- Taking this product may cause an erection that lasts longer than 4 hours. If an erection lasts longer than 6 hours, delaying treatment may permanently damage your ability to get an erection. If an erection lasts longer than 4 hours, see a doctor right away.
- If you need medical care for symptoms such as angina after taking this product, be sure to tell your doctor or pharmacist that you have taken this product.
- Use caution when working at heights or driving or operating vehicles or machinery after taking this product (symptoms such as dizziness or blurred vision may occur).

How this product improves quality of life

ED can have a major impact on quality of life. It can also affect your sexual and emotional relationship with your partner and may make it more difficult to maintain a close relationship. Effective treatment for ED can improve sexual satisfaction for both you and your partner. It can also help improve your overall quality of life by improving your self-esteem and strengthening your relationship.

Regular health checkups are important

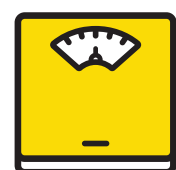
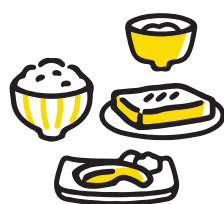
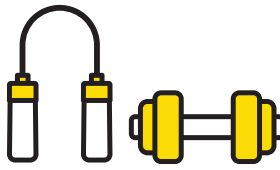
- ED can sometimes **be caused by underlying health conditions**, such as heart disease, high blood pressure, diabetes, or depression. Regular health checkups are recommended to help you stay healthy.

When should I seek medical care?

- It is recommended that you see your doctor as soon as possible after you start taking this product, ideally within 6 months.
- It is important to make sure you do not have an underlying condition, such as cardiovascular disease or diabetes, that could be causing your ED. Even if this product is working for you, it is important to have your condition evaluated objectively by your doctor. Ask your doctor whether you should continue taking this product.
- If this product is not working for you, or if you are experiencing symptoms that may be side effects, visit the medical facility or specialist referred by a pharmacist.

Healthy lifestyle habits are also important

- Consider making the following changes to improve your lifestyle and reduce your risk of ED:

Quit smoking	Drink alcohol in moderation	Avoid recreational drugs	Maintain a healthy weight (men with obesity are at higher risk of ED)
			
Eat a healthy diet	Exercise regularly	Reduce stress	
			

Other information

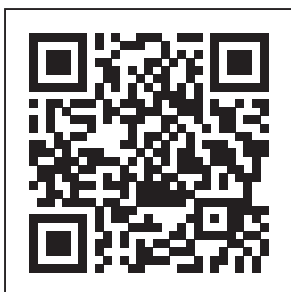
- Store this product in a cool, dry place away from direct sunlight.
- Keep this product out of the reach of children.
- Do not transfer the tablets to another container.
- Do not take this product after the expiration date.

Where can I get more information about this product?

- If you have questions about this product, please use the following Contact Form.

SSP Co., Ltd. Contact Form
<https://www.ssp.co.jp/contact/>

Be sure to review the helpful information posted on the product page on the SSP website as well.



Information will also be shared on the official LINE account for SSP*. Please friend us to get information that will help make your purchasing experience easier.
*Information on the official LINE account will only be available in Japanese.



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