

Package leaflet: information for the user

Tadalafil CF 5 mg, film-coated tablets

tadalafil

Read the entire leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Tadalafil CF and what is it used for?

This medicine contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

This medicine is used to treat adult men with erectile dysfunction. This occurs when a man cannot get or keep an erection firm enough for sexual activity. Tadalafil has been shown to significantly improve the ability to achieve an erection suitable for sexual activity.

After sexual stimulation, this medicine helps relax the blood vessels in the penis, allowing blood to flow into your penis. This improves your erection.

This medicine does not work if you do not have erectile dysfunction. It is important to know that this medicine does not work without sexual stimulation. You and your partner should know that foreplay is necessary, just as you would do if you were not using a medicine for erectile dysfunction.

symptoms of the urinary tract related to a common condition called benign prostatic hyperplasia (benign enlargement of the prostate). This means that the prostate gland becomes larger with age. Symptoms include difficulty urinating, feeling that the bladder is not completely empty, and needing to urinate more often, even at night. This medicine improves blood flow to the prostate and bladder and relaxes the muscles of these organs; this can reduce the symptoms of benign prostatic hyperplasia. It has been shown that this medicine improves these urinary symptoms from 1 to 2 weeks after starting treatment.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You are using an organic nitrate in any form or a medicine that releases nitric oxide such as amyl nitrite. Nitrates belong to a group of medicines used to treat angina pectoris (a tight, pressing, painful feeling in the chest). It has been shown that this medicine enhances the effects of these medicines. If you are using nitrate in any form or are unsure if you are, tell your doctor.

You have a severe heart condition or have had a heart attack in the past 90 days.

You have had a stroke in the past 6 months.

You have low blood pressure or high blood pressure that is not controlled.

You have ever had a loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "eye paralysis".

You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (this is increased blood pressure in the pulmonary arteries) and chronic thromboembolic pulmonary hypertension (this is increased blood pressure in the pulmonary arteries due to blood clots). PDE5 inhibitors, such as this medicine, have been shown to enhance the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure about it, contact your doctor.

When should you be extra careful with this medicine?

Contact your doctor before using this medicine.

Be aware that sexual activity can be risky for patients with a heart condition, as this activity requires extra effort from your heart. If you have a heart condition, tell your doctor.

Because benign prostatic hyperplasia and prostate cancer can have the same symptoms, your doctor will check you for prostate cancer before starting treatment with this medicine for benign prostatic hyperplasia.

This medicine is not used for the treatment of prostate cancer.

Tell your doctor before taking the tablets if you have any of the following conditions:

sickle cell anemia (a disorder of the red blood cells).

multiple myeloma (bone marrow cancer).

leukemia (blood cell cancer).

a deformity of your penis.

a severe liver problem.

a severe kidney problem.

It is not known if this medicine is effective in patients who:

have undergone pelvic surgery.

have undergone complete or partial removal of the prostate gland, where the nerve pathways of the prostate have been severed (radical non-nerve-sparing prostatectomy).

If you suddenly notice a decrease or loss of vision, or if your vision becomes distorted or blurred while using this medicine, stop taking this medicine and contact your doctor immediately.

Sudden decrease in hearing or hearing loss has been observed in some patients after using tadalafil. Although it is not known if these cases are directly related to tadalafil, you should contact your doctor as soon as you notice a sudden decrease in hearing or hearing loss.

This medicine is not intended for use by women.

Children and adolescents under 18 years

This medicine is not intended for use by children and adolescents under 18 years.

Are you taking any other medicines?

Are you taking any other medicines besides Tadalafil CF, have you recently done so, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor.

Do not take this medicine if you are already taking nitrates.

Some medicines are affected by this medicine or can affect how this medicine works. Tell your doctor or pharmacist if you are already taking the following medicines:

- an alpha-blocker (used to treat high blood pressure or urinary problems associated with benign prostatic hyperplasia).

- other medicines to treat high blood pressure.

- riociguat.

- a 5-alpha reductase inhibitor (used for the treatment of benign prostatic hyperplasia).

- medicines such as ketoconazole tablets (to treat a fungal infection) and protease inhibitors for the treatment of AIDS or HIV infection.

- phenobarbital, phenytoin, and carbamazepine (medicines to treat seizures).

- rifampicin, erythromycin, clarithromycin, or itraconazole.

- other treatments for erectile dysfunction.

What should you be aware of with drinking and alcohol?

See section 3 for information on the effect of alcohol use. Grapefruit juice may affect how well this medicine works and should be taken with caution. Ask your doctor for more information about this.

Fertility

In animal studies, there was reduced sperm production in the testes. A reduction in sperm has also been seen in some men. It is unlikely that these effects will lead to infertility.

Driving and using machines

Some men who took this medicine in clinical studies reported dizziness. Carefully check how you react to the tablets before driving or operating machinery.

Tadalafil CF contains lactose

If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

Tadalafil CF contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, meaning it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Method of use

This medicine is intended for oral use by men only. Swallow the tablet whole with some water. You can take the tablets with or without food.

Do not take this medicine more than once a day.

Drinking alcohol can temporarily lower your blood pressure. If you have taken this medicine or plan to take it, avoid excessive drinking (e.g., more than 900 ml of beer or 350 ml of wine), as this may increase the risk of dizziness upon standing.

For the treatment of erectile dysfunction

Dosage

The recommended dose is one 5 mg tablet once daily at approximately the same time each day. Your doctor may adjust the dose to 2.5 mg depending on your response to this medicine. This will be given as a 2.5 mg tablet.

The recommended dosages are not all possible with the 5 mg tablet, but tadalafil tablets of 2.5, 10, and 20 mg are also available. Not all strengths may be marketed.

Note

When you take this medicine once a day, you are able to get an erection at any time during the 24 hours of the day when sexually stimulated. Once-daily use of this medicine may be useful for men who expect to be sexually active two or more times a week.

It is important to know that this medicine does not work without sexual stimulation. You and your partner should know that foreplay is necessary, just as you would do if you were not taking a medicine for erectile dysfunction.

Drinking alcohol can affect your ability to get an erection.

For the treatment of benign prostatic hyperplasia

Dosage

The dose is one 5 mg tablet to be taken once daily at approximately the same time of day. If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet per day.

Do not take this medicine more than once a day.

Have you used too much of this medicine?

Contact your doctor. You may experience side effects as described in section 4.

Have you forgotten to use this medicine?

Take your dose as soon as you remember, but do not take a double dose to make up for a forgotten tablet. You should not take this medicine more than once a day.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. These side effects are usually mild to moderate in nature.

If you experience any of the following side effects, stop taking the medicine and seek medical help immediately:

allergic reaction including rash (occur in less than 1 in 100 users).

chest pain. Do not use nitrates but seek medical help immediately (occur in less than 1 in 100 users).

priapism, a prolonged and possibly painful erection after taking this medicine (occur in less than 1 in 1000 users). If you have such an erection and it lasts longer than 4 hours, contact your doctor immediately.

you may suddenly lose vision (occur in less than 1 in 1000 users), distorted, blurred, hazy central vision or sudden decreased vision (frequency not known).

Other reported side effects include:

Common (occur in less than 1 in 10 users)

headache

back pain

muscle pain, pain in arms and legs

facial flushing

nasal congestion and indigestion.

Uncommon (occur in less than 1 in 100 users)

dizziness

abdominal pain

nausea

vomiting

a burning sensation in the esophagus

blurred vision

eye pain

difficulty breathing

presence of blood in the urine

prolonged erection

palpitations

a rapid heartbeat

high blood pressure

low blood pressure

nosebleeds

ringing in the ears

swelling of hands, feet, and ankles

a tired feeling.

Rare (occur in less than 1 in 1000 users)

- fainting
- seizures
- transient memory loss
- swelling of the eyelids
- red eyes
- sudden decrease or loss of hearing
- hives (an itchy skin rash with bumps)
- bleeding from the penis
- presence of blood in the semen
- increased sweating.

A heart attack and stroke have also been rarely reported in men using this medication. Most of these men already had heart problems before taking this medicine.

There have been rare reports of partial, temporary, or permanent decrease or loss of vision in one or both eyes.

Other side effects have been reported that rarely occur in men taking this medication and were not seen during clinical trials. These include:

- migraine
- swelling of the face
- severe allergic reaction causing swelling of the face and throat
- severe skin rash
- certain disorders related to blood supply to the eyes
- irregular heartbeat
- tight, pressing, painful feeling in the chest (angina pectoris)
- sudden cardiac arrest resulting in death
- distorted, blurred, hazy central vision or sudden reduction of vision (frequency unknown).

The side effect dizziness is more frequently reported in men over 75 years using this medication. The side effect diarrhea is more frequently reported in men over 65 years using this medication.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box and the blister pack after "EXP". It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is tadalafil.
Each film-coated tablet contains 5 mg tadalafil.

The other substances in this medicine are:

Tablet core:

lactose monohydrate
croscarmellose sodium
sodium lauryl sulfate (E487)
hydroxypropyl cellulose
polysorbate
microcrystalline cellulose
magnesium stearate

Film coating:

hypromellose
lactose monohydrate
titanium dioxide (E171)
triacetin
yellow iron oxide (E172)
talc

What does Tadalafil CF look like and how many are in a package?

Light yellow, round, biconvex, film-coated tablet, with a diameter of 6.1 ± 0.2 mm.

Available in blister packs of 14x1, 28x1, 30x1, 56x1, and 84x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Netherlands

Manufacturer

STADA Arzneimittel AG
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61118 Bad Vilbel
Germany

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Registered in the register under
RVG 124325, Tadalafil CF 5 mg, film-coated tablets

This medicine is registered in EEA member states under the following names:

Germany	Tadalafil AL 5 mg Filmtabletten
Italy	TADALAFIL EG STADA 5 mg compresse rivestite con film
Iceland	Tadalafil Stada 5 mg filmuhúðaðar töflur
Netherlands	Tadalafil CF 5 mg, film-coated tablets
Portugal	Tadalafil Ciclum Farma
Czech Republic	Tadalafil Stada 5 mg film-coated tablets

This leaflet was last approved in June 2025.