

Package leaflet: Information for the user

Tadalafil CF 10 mg, film-coated tablets

Tadalafil CF 20 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 for you only. 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:

an erectile dysfunction. This occurs when a man cannot get an erection or cannot maintain an erection long enough for sexual activity. It has been shown that tadalafil significantly improves 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.

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

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 for the treatment of 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 serious 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 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 increase 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.

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

sickle cell anemia (an abnormality of red blood cells).

multiple myeloma (bone marrow cancer).

leukemia (blood cell cancer).

a deformity of your penis.

a serious liver problem.

a serious 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 hearing loss or hearing impairment 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 sudden hearing loss or hearing impairment.

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 symptoms 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 observed 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 have an intolerance to some 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.

Dosage

The recommended starting dose is 10 mg tadalafil before sexual activity.

If the effect of this dose is too low, your doctor may increase the dose to 20 mg.

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

Method of administration

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

The tablets can be divided into equal doses

The 20 mg tablet can be divided as follows: press the tablet down with one finger on a firm surface to break the tablet.

You can take this medicine at least 30 minutes before sexual activity. This medicine can still be effective up to 36 hours after taking the tablet.

Do not take this medicine more than once a day. Doses of 10 mg and 20 mg are intended for use before anticipated sexual activity and are not recommended for continuous daily use.

Note

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.

Drinking alcohol can affect your ability to get an erection and can temporarily lower your blood pressure. If you have taken this medicine or if you plan to take this medicine, avoid excessive drinking (e.g., more than 900 ml of beer or 350 ml of wine), as this may increase the risk of dizziness when standing up.

Have you used too much of this medicine?

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

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 are:

Common (occur in less than 1 in 10 users)

- headache
- back pain
- muscle pain, pain in arms and legs
- flushing of the face
- nasal congestion and indigestion.

Sometimes (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
- tinnitus
- swelling of hands, feet, and ankles
- a feeling of fatigue.

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 semen
- increased sweating.

A heart attack and stroke have also been rarely reported in men taking 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 the face and throat to swell
severe skin rash
certain disorders related to the 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 not known).

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

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. You can find it 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.
Broken tablets should be discarded after 4 weeks of storage.

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 10 or 20 mg of 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 much is in a package?

Tadalafil CF 10 mg, film-coated tablets

Yellow, round, biconvex, film-coated tablet with a score line on one side, white inside at the break line, with a diameter of 8.1 ± 0.2 mm. The tablet can be divided into equal doses.

Tadalafil CF 20 mg, film-coated tablets

Yellow, round, biconvex, film-coated tablet with a cross score on both sides, white inside at the break line, with a diameter of 10.1 ± 0.2 mm. The tablet can be divided into equal doses.

Tadalafil CF 10 mg, film-coated tablets

Available in blister packs of 4x1, 8x1, 12x1, 24x1, 36x1, and 48x1 film-coated tablets.

Tadalafil CF 20 mg, film-coated tablets

Available in blister packs of 2x1, 4x1, 8x1, 12x1, 24x1, 36x1, and 48x1 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
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Manufacturer

STADA Arzneimittel AG
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Registered in the register under
RVG 124326, Tadalafil CF 10 mg, film-coated tablets
RVG 124327, Tadalafil CF 20 mg, film-coated tablets

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

Germany	Tadalafil AL 10 mg Filmtabletten Tadalafil AL 20 mg Filmtabletten
Iceland	Tadalafil Stada 10 mg film-coated tablets Tadalafil Stada 20 mg film-coated tablets
Italy	TADALAFIL EG STADA 10 mg film-coated tablets TADALAFIL EG STADA 20 mg film-coated tablets
Netherlands	Tadalafil CF 10 mg, film-coated tablets Tadalafil CF 20 mg, film-coated tablets
Portugal	Tadalafil Ciclum Farma
Czech Republic	Tadalafil Stada 20 mg film-coated tablets

This leaflet was last approved in June 2025.