

CALIBERI[®] ORODISPERSIBLE FILM

Tadalafil (5mg and 20mg)

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What Caliberi[®] is used for

Caliberi[®] 5mg and 20mg are used to treat adult men with:

- **erectile dysfunction.** This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Caliberi[®] has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

Caliberi[®] 5mg is used to treat adult men with:

- urinary symptoms associated with a common condition called **benign prostatic hyperplasia**. This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night.

How Caliberi[®] works

Caliberi[®] contains the active ingredient tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE 5 inhibitors).

Following sexual stimulation Caliberi[®] works by helping the blood vessels in your penis to

relax, allowing the flow of blood into your penis. The result of this is improved erectile function. Caliberi[®] will not help you if you do not have erectile dysfunction. It is important to note that Caliberi[®] for the treatment of erectile dysfunction does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Caliberi[®] improves blood flow to, and relaxes, the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Caliberi[®] has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

Before you use Caliberi[®]

- When you must not use it

Do not take Caliberi[®] if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (see section **Product Description**).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines (nitrates) used in the treatment of angina pectoris (chest pain). Caliberi[®] has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.

- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e. high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Caliberi[®], have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

- Before you start to use it

Talk to your doctor before taking Caliberi[®].

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor.

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with Caliberi[®] for benign prostatic hyperplasia. Caliberi[®] does not treat prostate cancer.

Before taking the films, tell your doctor if you have:

- sickle cell anaemia (an abnormality of red blood cells).

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- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis.
- a serious liver problem.
- a severe kidney problem.

It is not known if Caliberi® is effective in patients who have had:

- pelvic surgery
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy)

Caliberi® is not intended for use by women.

Children and adolescents

Caliberi® is not intended for use by children and adolescents under the age of 18.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines

Do not take Caliberi® if you are already taking nitrates.

Some medicines may be affected by Caliberi® or they may affect how well Caliberi® will work. Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia [benign enlargement of the prostate]).
- other medicines to treat high blood pressure.
- riociguat

- a 5-alpha reductase inhibitor (used to treat benign prostatic hyperplasia)
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

How to use Caliberi®

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Caliberi® is for oral use in men only.

For the treatment of erectile dysfunction

The recommended dose is one 5mg film or 20mg film taken once a day at approximately the same time of the day before meal. Do not take Caliberi® more than once a day.

For the treatment of benign prostatic hyperplasia

The dose is one 5mg film taken once a day at approximately the same time of the day before meal. If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5mg film taken once a day. Do not take Caliberi® more than once a day.



Open the sachet from top



Roll down the back side of the sachet. You can see a thin film edge after rolling down.



Pull the film edge and remove the thin film from the sachet and place it immediately on your tongue. Allow it to dissolve.

When to use it

You may take a Caliberi® before sexual activity. Caliberi® may still be effective up to 36 hours after taking.

- How long to use it

For the treatment of erectile dysfunction

When taken once a day Caliberi® allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of Caliberi® may be useful to men who anticipate having sexual activity two or more times a week

For the treatment of benign prostatic hyperplasia

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Continue taking Caliberi[®] for as long as your doctor recommends.

- If you forget to use it

Take your dose as soon as you remember but do not take double dose to make up for a forgotten dose.

You should not take Caliberi[®] more than once a day.

- If you use too much (overdose)

Contact your doctor. You may experience side effects (see section **Side Effects**).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using it

- Things you must do

If you experience sudden decrease or loss of vision, stop taking Caliberi[®] and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Caliberi[®] and contact your doctor immediately.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Driving and using machines
Some men taking Caliberi[®] in clinical studies have reported dizziness. Check carefully how

you react to the film before driving or using machines.

Caliberi[®] with drinks and alcohol

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Caliberi[®], avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

Grapefruit juice may affect how well Caliberi[®] will work and should be taken with caution. Talk to your doctor for further information.

Fertility

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility

Side effects

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

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

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency very rare).
- Priapism, a prolonged and possibly painful erection after taking Caliberi[®] (frequency very rare). If you have such an

erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.

- sudden loss of vision (frequency rare).

Other side effects have been reported:

Common (seen in 1 to 10 in every 100 patients)

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, indigestion and reflux.

Uncommon (seen in 1 to 10 in every 1,000 patients)

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired

Rare (seen in 1 to 10 in every 10,000 patients)

- Fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking Caliberi[®]. Most of these men had known heart problems before taking this medicine.

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Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional very rare side effects have been reported in men taking Caliberi[®] that were not seen in clinical trials. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

The side effect dizziness has been reported more frequently in men over 75 years of age taking Caliberi[®]. Diarrhoea has been reported more frequently in men over 65 years of age taking Caliberi[®].

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550 or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Caliberi[®]

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Caliberi[®] Orodispersible Film 5mg and 20mg are light yellow, rectangular orodispersible film

- Ingredients

- Active ingredient

Each film contains 5mg or 20mg Tadalafil

- Inactive ingredients

Hydroxypropyl cellulose, Xanthan gum, Glycerin, Polyethylene glycol 400, Mannitol, Simethicone emulsion (30%), Titanium dioxide, Polysorbate 80, Sucralose, Ferric oxide-yellow, Ferric oxide-red, Vanilla flavor and Purified Water

- MAL number:

Caliberi Orodispersible Film 5mg:
MAL21036001AZ

Caliberi Orodispersible Film 20mg:
MAL21036002AZ

Manufacturer

CTCBio Inc

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Product Registration Holder
Abbott Laboratories (M) Sdn. Bhd.

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