

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EXCELVIOR 5 FILM COATED TABLETS

EXCELVIOR 20 FILM COATED TABLETS

Tadalafil

Contains lactose monohydrate

Read all of this leaflet carefully before you start taking EXCELVIOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EXCELVIOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What EXCELVIOR is and what it is used for
2. What you need to know before you take EXCELVIOR
3. How to take EXCELVIOR
4. Possible side effects
5. How to store EXCELVIOR
6. Contents of the pack and other information

1. What EXCELVIOR is and what it is used for

EXCELVIOR contains a medicine called tadalafil. This belongs to a group of medicines called phosphodiesterase type 5 inhibitors. EXCELVIOR is a treatment for adult males who cannot get, or keep a hard, erect penis suitable for sexual activity (erectile dysfunction). EXCELVIOR does not work if there is no sexual stimulation. Following sexual stimulation EXCELVIOR works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis

EXCELVIOR is used to:

- significantly improve the ability of obtaining a hard erect penis suitable for sexual activity;

2. What you need to know before you take EXCELVIOR

Do not take EXCELVIOR:

- If you are hypersensitive (allergic) to tadalafil or any of the other ingredients of this medicine (listed in section 6);
- If you are taking organic nitrate to treat angina pectoris (chest pains);
- If you have serious liver disease;
- If you have ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- If you have ever had decreased or sudden loss of hearing

Warnings and precautions

Talk to your doctor or health care provider before using EXCELVIOR.

Take special care with EXCELVIOR if:

- You have ever had heart problems (sexual activity carries possible risk to patients with heart disease and tadalafil is known to cause a decrease in blood pressure);
- You have had a heart attack within the last 90 days;
- You experience chest pains during sexual intercourse;

- You recently had a stroke within the last 6 months
- You have low blood pressure or uncontrolled high blood pressure
- You have sickle cell anaemia (an abnormality of red blood cells);
- You have multiple myeloma (cancer of the bone marrow);
- You have leukaemia (cancer of the blood cells);
- You have any deformation of your penis;
- You have serious liver problem;
- You suffer from kidney impairment.

Stop taking EXCELVIOR and contact your doctor immediately if you experience sudden decrease or loss of vision.

Some patients taking tadalafil have reported sudden decrease or loss of hearing. Stop taking EXCELVIOR and contact your doctor or health care provider.

The safety and efficacy of combinations of PDE5 inhibitors (medicines that increase blood flow to the penis to improve erectile function) has not been determined. You should not take such combinations.

EXCELVIOR is not intended for use by women.

EXCELVIOR is not intended for use by children and adolescents.

Other medicines and EXCELVIOR

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Please inform your healthcare professional if you are currently taking any of the following medicines:

- Do not take EXCELVIOR if you are already taking nitrates
- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia);

- other medicines to treat high blood pressure;
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection;
- rifampicin, erythromycin, clarithromycin or itraconazole;
- other treatments for erectile dysfunction;
- Grapefruit juice may affect how well EXCELVIOR will work and should be taken with caution
- EXCELVIOR may increase your levels of ethinylestradiol (used in oral contraceptives); a similar increase may be expected with terbutaline (used to prevent and treat wheezing, shortness of breath, and chest tightness caused by asthma, chronic bronchitis, and emphysema).

Pregnancy and breastfeeding

EXCELVIOR is not intended for use by women

Driving and using machines

EXCELVIOR may cause blurred vision and dizziness which may affect your ability to drive or operate machines.

It is not always possible to predict to what extent EXCELVIOR may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which EXCELVIOR affects you.

EXCELVIOR contains lactose monohydrate

EXCELVIOR contains lactose (milk sugar). If you have been told that you have an intolerance to some sugars, contact your doctor before taking EXCELVIOR.

3. How to take EXCELVIOR

Do not share medicines prescribed for you with any other person. Always take EXCELVIOR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In adult men

EXCELVIOR is for oral use in men only. Tablets can be taken with or without food.

EXCELVIOR 5: The recommended dose is 5 mg taken once a day at approximately the same time of day.

EXCELVIOR 20: The recommended maximum dose is 20 mg taken prior to anticipated sexual activity and without regard to food.

It can be taken as early as 16 minutes prior to sexual activity and may still be effective up to 36 hours after taking the tablet. You could initiate sexual activity at varying time points relative to taking the tablet in order to determine your own optimal window of responsiveness.

The maximum recommended dosing frequency is once per day.

It is important to note that EXCELVIOR does not work if there is no sexual stimulation.

In men with impaired kidney function

It is not necessary to adjust your dose if you have mild or moderate kidney impairment. Once-a-day dosing of EXCELVIOR is however not recommended if you suffer from severe kidney disease.

Method of administration

EXCELVIOR is for oral use in men only. Swallow the tablets whole with water. Tablets can be taken with or without food.

Your doctor will tell you how long your treatment with EXCELVIOR will last. If you have the impression that the effect of EXCELVIOR is too strong or too weak, tell your doctor or pharmacist.

If you take more EXCELVIOR than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take EXCELVIOR

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

EXCELVIOR can have side effects.

Not all side effects reported for EXCELVIOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EXCELVIOR, please inform your health care provider for advice.

If any of the following happens, stop taking EXCELVIOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EXCELVIOR. You may need urgent medical attention.

Tell your doctor or health care provider if you notice any of the following:

Frequent side effects:

- Headache;
- Flushing;
- Nasal congestion;
- Indigestion.

Less frequent side effects:

- Dizziness;
- Stroke (including bleeding in the brain) and mini-stroke;
- Fainting;
- Migraine;
- Seizures;
- Passing memory loss;
- Blurred vision;
- Eye pain;
- Ringing in the ears;
- Sudden decrease or loss of hearing;
- Pounding heartbeat sensation;
- A fast heart rate;
- Heart attack;
- Sudden chest pain;
- Abnormal heartbeats in the lower chambers of the heart (ventricular dysrhythmia);
- Low blood pressure;
- High blood pressure;

- Shortness of breath;
- Nosebleeds;
- Abdominal pain;
- Feeling sick, being sick (vomiting);
- Acid reflux;
- Rash, hives;
- Sweating;
- Red, peeling skin;
- Back pain;
- Muscle pain.
- Prolonged erections
- Painful erections
- Penile bleeding
- Presence of blood in ejaculate

Side effects with unknown frequency:

- Changes in vision, sudden loss of vision;
- Swollen eyelids;
- Red eyes;
- Retinal vein blockage.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of EXCELVIOR.

5. How to store EXCELVIOR

Store all medicines out of sight and reach of children.

Store at or below 25 °C.

Store in the original package.

Keep the blisters in the outer carton.

Do not store in a bathroom.

Do not use EXCELVIOR after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What EXCELVIOR contains

- **EXCELVIOR 5:** Each film coated tablet contains 5 mg tadalafil.
Contains lactose monohydrate: 60 mg.
- **EXCELVIOR 20:** Each film coated tablet contains 20 mg tadalafil.
Contains lactose monohydrate: 240 mg.
- The other ingredients are lactose monohydrate, low-substituted hydroxypropyl cellulose, hydroxy propyl cellulose, sodium lauryl sulphate, cellulose, microcrystalline, magnesium stearate and Instacoat Aqua III (hypromellose, lactose monohydrate, triacetin, talc, titanium dioxide (E171), yellow iron oxide (E172)).

What EXCELVIOR looks like

EXCELVIOR 5: Yellow, 8.00 mm x 4.90 mm, almond shaped, film coated tablet, debossed with 'T5' on one side and plain on other side.

EXCELVIOR 20: Yellow, 12.25 mm x 7.45 mm, almond shaped, film coated tablet, debossed with 'T20' on one side and plain on other side.

EXCELVIOR 5: PVC/PVDC/PE/Alu blister packs containing 28 tablets.

EXCELVIOR 20: PVC/PVDC/PE/Alu blister packs containing 2 or 4 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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2031

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