PATIENT INFORMATION LEAFLET FOR TALVIOR 5

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

TALVIOR 5 film coated tablets.

Read all of this leaflet carefully before you start taking TALVIOR 5

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TALVIOR 5 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.

1. WHAT TALVIOR 5 CONTAINS

The active ingredient is 5 mg tadalafil.

Other ingredients are: Colloidal silicone dioxide, croscarmellose sodium (Ac-Di-Sol), hydroxypropyl cellulose, magnesium stearate (Kosher Passover HyQual), Opadry Yellow (containing hypromellose, iron oxide yellow, macrogol, talc and titanium dioxide), povidone K-25 and sodium lauryl sulphate.

Contains sugar: Lactose monohydrate, 81,70 mg.

2. WHAT TALVIOR 5 IS USED FOR

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

TALVIOR 5 is used to treat erectile dysfunction (when a man cannot get or keep a hard, erect penis suitable for sexual activity) in adult men.

It is important to note that sexual stimulation is required for **TALVIOR 5** to work for the treatment of erectile dysfunction.

3. BEFORE YOU TAKE TALVIOR 5

Do not take TALVIOR 5:

- If you are hypersensitive (allergic) to tadalafil or any of the other ingredients of TALVIOR 5 (see **WHAT TALVIOR 5 CONTAINS**).
- If you are taking any form of organic nitrate (used to treat angina (chest pain) or heart attack).
- If you have a severe liver problem.
- If you have or previously experienced partial, sudden, temporary or permanent loss of vision in one or both of your eyes.
- If you previously experienced a decrease or total loss of hearing, in one or both of your ears.

Take special care with TALVIOR 5:

Tell your doctor or healthcare provider before taking TALVIOR 5:

- If you have any heart problem. Especially if your doctor has instructed you not to engage in sexual activity. Sexual activity carries a possible risk to patients with heart disease because it puts extra strain on your heart.
- If you had a heart attack within the last 90 days.
- If you suffer from chest pains, especially if you experience chest pain during sexual intercourse.
- If you suffer from heart failure.
- If you have an abnormal heart beat.
- If you have low blood pressure.
- If you have uncontrolled high blood pressure.
- If you had a stroke within the last 6 months.
- If you have previously been diagnosed with non-arteritic anterior ischaemic optic neuropathy (NAION) (a condition known as “stroke of the eye” causing loss of vision). Inform your doctor immediately if you experience any problems with your eyesight.
- If you are older than 50 years of age.
- If you suffer from coronary artery disease (heart disease causing blockage of the blood vessels to your heart).
- If you suffer from “crowded disc”, a condition affecting your eyes.
- If you smoke.
- If you experience a sudden loss of hearing, associated with ringing in your ears or dizziness. Inform your doctor as soon as possible.
- If you are taking any other medicine to treat erectile dysfunction.

- If you experience a persistent or painful erection. Inform your doctor immediately if you experience a long-lasting erection for more than 4 hours.
- If you have an anatomical deformity of your penis.
- If you have sickle cell anaemia (an abnormality affecting your red blood cells).
- If you have multiple myeloma (cancer of your bone marrow).
- If you have leukaemia (cancer affecting your blood cells).
- If you suffer from severe kidney disease.
- If you suffer from any liver problem.
- If you have a stomach ulcer.
- If you suffer from a bleeding disorder.

Taking TALVIOR 5 with food, drink and alcohol:

TALVIOR 5 can be taken with or without food.

Grapefruit juice may increase the effects of TALVIOR 5 and should be taken with caution.

Drinking alcohol while taking TALVIOR 5 may temporarily lower your blood pressure and increase your risk of headache and dizziness, especially when standing up.

You should avoid excessive drinking of alcohol when taking TALVIOR 5.

Pregnancy and breastfeeding:

Safety in pregnancy and lactation has not been established.

TALVIOR 5 is not indicated for use in female patients.

Driving and using machinery:

TALVIOR 5 can cause side effects such as dizziness or problems with your eyesight and may impair your ability to drive a vehicle and use machinery. Do not drive a vehicle, operate machinery, or do anything else that require your attention until you know how TALVIOR 5 affects you.

Important information about some of the ingredients of TALVIOR 5:

TALVIOR 5 contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take TALVIOR 5.

Taking other medicines with TALVIOR 5:

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

The following medicines may cause an interaction when used in combination with TALVIOR 5:

- Ketoconazole or itraconazole (used to treat fungal infections).
- Ritonavir or saquinavir (used to treat HIV).
- Erythromycin or clarithromycin (used to treat bacterial infections).
- Rifampicin (used to treat tuberculosis (TB)).
- Carbamazepine, phenytoin or phenobarbitone (used to treat seizures).
- Antihypertensive medicine (e.g. riociguat) or alpha-adrenergic blockers (used to treat high blood pressure).
- Nitrates (used to treat angina (chest pain) or heart attack).
- Erectile dysfunction medicine.
- Antacids (used to treat heartburn, indigestion or stomach ulcers).
- Ethinylestradiol (an estrogen medicine used for birth control).
- Terbutaline (used to treat asthma).

4. HOW TO TAKE TALVIOR 5

Do not share medicine prescribed for you with any other person.

Always take TALVIOR 5 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 5 mg taken once a day, at approximately the same time of the day.

If you have the impression that the effect of TALVIOR 5 is too strong or too weak, talk to your doctor or pharmacist.

If you take more TALVIOR 5 than you should:

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

Take this leaflet and the remaining tablets with you so the doctor will know what you have taken.

If you forget to take a dose of TALVIOR 5:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take TALVIOR 5 at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

TALVIOR 5 can have side effects.

Not all side effects reported for TALVIOR 5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TALVIOR 5, please consult your healthcare provider for advice.

If any of the following happens, stop taking TALVIOR 5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, 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 allergic reaction to TALVIOR 5. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent side effects:

- Angina (chest pain).
- Heart attack (pain or discomfort in your chest or arm/s, shortness of breath, feeling anxious, sweating, nausea or vomiting).
- Changes in the way your heart beats (beating faster than normal or skipping beats).
- A bacterial skin infection (where you experience pain, redness and swelling of the skin with chills or fever).
- Signs of recurrent infections, such as fever or sore throat.

- Seizures (fits).
- Non-arteritic anterior ischaemic optic neuropathy (sudden painless loss of vision, blurred vision).
- Stroke (sudden numbness or weakness on one side of your body, difficulty speaking or difficulty walking).
- Painful, long-lasting erection.

Side effects of unknown frequency:

- Retinal vein occlusion (loss of vision).
- Loss of part of your usual field of vision.
- Severe, painful blistering skin rash known as exfoliative dermatitis or Stevens-Johnson syndrome.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Fever.
- Difficulty sleeping.
- Feeling anxious.
- Headache or dizziness.
- Blurred vision, sensitivity of your eyes to light, changes in colour vision including seeing everything tinted with blue, irritation of your eyes or eye pain.
- Vertigo (spinning feeling in your head).
- Flushing (redness of your skin).
- Blocked nose.
- Nose bleeds.
- Indigestion, diarrhoea or vomiting (being sick).
- Back pain or muscle pain.

Less frequent side effects:

- Infection of your lungs (coughing, production of sputum, fatigue or shortness of breath).
- Anaemia (tiredness, pale skin or weakness).
- Drowsiness.

- Loss of sensation.
- Paraesthesia (numbness, burning or tingling feeling of your skin).
- Sudden onset of memory loss and confusion.
- Inflammation of your eyes (“pink eyes”).
- Increased tearing of your eyes or swelling of your eyelids.
- Sudden decreased or loss of hearing.
- Ringing or buzzing noise in one or both ears (tinnitus) .
- High blood pressure or low blood pressure (light-headedness or dizziness).
- Fainting.
- Sudden drop in blood pressure when you stand up from a sitting or lying position (light-headedness or dizziness).
- Sore throat, runny nose, coughing or sinus infection (blocked nose and headache).
- Shortness of breath.
- Dry mouth.
- Difficulty swallowing.
- Inflammation of your stomach (nausea, vomiting, bloating or indigestion).
- Heartburn.
- Loose stools.
- Nausea (feeling sick).
- Pain of your upper stomach area.
- Sweating.
- Redness of your skin, rash.
- Hair loss.
- Joint pain, neck pain or pain in your limbs.
- Urinary tract infection (painful, burning urination and frequent urge to urinate).
- Frequent urination.
- Loss of bladder control (involuntary leakage of urine).
- Presence of blood in your urine.
- Spontaneous erection of your penis, prolonged erections.
- Enlargement of your breast tissues.
- Presence of blood in semen.

- Tiredness or weakness.
- Generalised pain.
- Fluid retention (swelling of your face, arms, hands, legs or feet).

Side effects of unknown frequency:

- Migraine (severe headache).

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

6. STORING AND DISPOSING OF TALVIOR 5

- Store at or below 30 °C.
- Protect from light and moisture.
- Store in original packaging.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF TALVIOR 5

OPA/Alu/PVC/aluminium blister strips or clear PVC/Aclar/aluminium blister strips containing 8, 10, 28 or 30 tablets. The blister strips are packed in an outer carton.

8. IDENTIFICATION OF TALVIOR 5

Yellow to light yellow, round shaped, bevelled edge, film coated tablets debossed with “337” on one side and plain on the other side.

9. REGISTRATION NUMBER

50/7.1.5/0661

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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