HOVID ERETAF ORODISPERSIBLE FILMS (ODF)

Tadalafil (10mg, 20mg)

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What Hovid Eretaf Orodispersible Films (ODF) is used for

Hovid Eretaf ODF is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

How Hovid Eretaf ODF works

Hovid Eretaf ODF contains the active ingredient tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE 5 inhibitors).

Following sexual stimulation tadalafil 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. Tadalafil will not help you if you do not have erectile dysfunction. It is important to note that treatment 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.

Before you use Hovid Eretaf ODF

- *When you must not use it*

Do not take Hovid Eretaf ODF 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"). Hovid Eretaf ODF 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 a 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 Hovid Eretaf ODF, 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 Hovid Eretaf ODF.

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.

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

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

Hovid Eretaf ODF is not intended for use by women.

Children and adolescents: Hovid Eretaf ODF 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 Hovid Eretaf ODF if you are already taking nitrates.

Some medicines may be affected by Hovid Eretaf ODF or they may affect how well Hovid Eretaf ODF 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 Hovid Eretaf ODF

- *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.

The recommended starting dose is 10 or 20 mg taken before sexual activity. Your doctor will decide the suitable dose for you.

- *When to use it*

Hovid Eretaf ODF are for oral use in men only. Place Hovid Eretaf ODF on top of tongue. The ODF can be taken without food.

You may take a Hovid Eretaf ODF at least 30 minutes before sexual activity. Hovid Eretaf ODF may still be effective up to 36 hours after taking the ODF.

- *How long to use it*

Do not take Hovid Eretaf ODF more than once a day.

- *If you forget to use it*

Hovid Eretaf ODF is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

- *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 Hovid Eretaf ODF and contact your doctor immediately.

Decrease 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 decrease or sudden hearing loss, stop taking Hovid Eretaf ODF and contact your doctor immediately.

- *Things you must not do*

This medicine had 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 Hovid Eretaf ODF have reported dizziness. Check carefully how you react to the ODF before driving or using machines.

Hovid Eretaf ODF 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 Hovid Eretaf ODF, 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 Hovid Eretaf ODF 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 uncommon).
- priapism, a prolonged and possibly painful erection after taking Hovid Eretaf ODF (frequency 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 tadalafil. Most of these men had known heart problems before taking this medicine.

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

Some additional rare side effects have been reported in men taking tadalafil 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 tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking tadalafil.

If you get any side effects, talk to your doctor or pharmacist. This includes 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 visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Hovid Eretaf ODF

- *Storage*

Keep out of the reach and sight 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

Hovid Eretaf ODF 10mg**:**
Yellow coloured, rectangular, opaque, non-sticky, orally disintegrating strip.

Hovid Eretaf ODF 20mg:
Yellow coloured, rectangular, opaque, non-sticky, orally orodispersible strip.

Presentation: Box of 4 films

- *Ingredients*
  - Active ingredient
    Hovid Eretaf ODF 10mg:
    Each orodispersible film contains 10mg of tadalafil.

    Hovid Eretaf ODF 20mg:
    Each orodispersible film contains 20mg of tadalafil.
  - Inactive ingredients
    Hypromellose, glycerol, polysorbate 80, propylene glycol, partly dementholised mint oil (limonene, cineole, L-menthone, iso-menthone, menthyl acetate, iso-pulegol, menthol, pulegone, carvone), sodium lauryl sulfate, sucralose, yellow oxide of iron, purified water.

- *MAL number:*
  Hovid Eretaf ODF 10mg:
  MALxxxxxxxxACZ

  Hovid Eretaf ODF 20mg:
  MALxxxxxxxxACZ

Manufacturer

Zim Laboratories Limited
B-21/22, MIDC Area, Kalmeshwa, Nagpur, Maharashtra State, 441501, India.

Product Registration Holder

Hovid Bhd.
121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar), 30010 Ipoh, Perak, Malaysia.

Date of revision

10/11/2022

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