

ERICFIL 100 mg Film Coated Tablet

Sildenafil (100 mg)

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What Ericfil is used for

Ericfil is a treatment for adult men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

How Ericfil works

Ericfil contains the active substance sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. Ericfil will only help you to get an erection if you are sexually stimulated.

Before you use Ericfil -

When you must not use it

- If you are taking medicines containing nitrates, nitrites or nitric oxide donors.
- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of Ericfil.
- If you are taking riociguat. This medicine 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 caused by blood clots).

Pregnancy and lactation

Ericfil is not indicated for use by women.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow) or any disease or deformity of your penis. These conditions may require special care when taking medicines for erectile dysfunction.
- If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.
- If you have obstruction with the pumping chambers of your heart.
- If you currently have a stomach ulcer, or a bleeding disorder (such as haemophilia).
- If you have or ever had a sudden decrease or loss of vision because of a problem with blood flow to the nerve in the eye called non-arteritic anterior ischaemic optic neuropathy (NAION).
- If you have low blood pressure at rest.
- If you have a rare inherited degenerative eye disease (retinitis pigmentosa).
- If you are on any other treatment for erectile dysfunction.
- If you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Special considerations for children:

Ericfil should not be given to children under the age of 18.

- Taking other medicines

Ericfil tablets may interfere with some medicines. In the event of a medical emergency, you should tell anyone treating your condition that you have taken Ericfil. Do not take Ericfil with other medicines unless your doctor tells you that you can.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly any of the following:

- Medicines containing nitrates, nitrites, and nitric oxide donors. Combination of this medicine and Ericfil may lead to low blood pressure.
- Protease inhibitors, such as ritonavir and saquinavir used for the treatment of HIV. Your doctor may start you on the lowest dose (25 mg) of Ericfil.
- Alpha-blocker therapy (e.g. doxazosin) for the treatment of high blood pressure or prostate problems as the combination of the two medicines may cause symptoms such as dizziness or light-headedness upon standing.
- Ketoconazole used to treat fungal infections.
- Erythromycin and rifampicin used to treat bacterial infections.
- Cimetidine used to treat and prevent certain types of ulcer.
- Bosentan and riociguat, used to treat high blood pressure.

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Taking Ericfil with food and drink

When Ericfil is taken with high fat food, it may take a little longer for Ericfil to work.

How to use Ericfil - ***How much to use***

Always take Ericfil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 50 mg. The maximum recommended daily dose is 100 mg and minimum dose is 25 mg.

Ericfil will only help you to get an erection if you are sexually stimulated. The amount of time Ericfil takes to work varies from person to person. You should not use Ericfil more than once a day.

- ***When to use it***

You should take Ericfil about one hour before sexual activity. Swallow the tablet whole with some water.

- ***How long to use it***

Continue taking Ericfil for as long as your doctor recommends.

- ***If you forget to use it***

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- ***If you use too much (overdose)***

A dose above 100 mg does not increase the efficacy. However, it will result in an increase in undesirable effects and their severity. You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

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

While you are using it

- ***Things you must do***

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Ericfil.

If Ericfil does not help you to get an erection or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

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

- ***Things you must not do***

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Ericfil to anyone else, even if they have the same symptoms or condition as you.

Drinking alcohol can temporarily impair the ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink large amounts of alcohol before taking Ericfil.

- ***Things to be careful of***

Driving and using machines

The effect of Ericfil on the ability to drive and use machinery has not been studied.

Ericfil can cause dizziness and can affect vision. You should be aware of how you react to Ericfil before you drive or use machinery.

Side effects

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

If any of the following happen, stop taking Ericfil and tell your doctor immediately:

- Headache
- Dizziness
- Vision blurred
- Visual disturbance
- A disorder of the vision causing all objects to appear blue (Cyanopsia)
- Hot flush and flushing
- Nasal congestion
- Nausea
- Indigestion

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor.

Ericfil TABLETS

Sildenafil Citrate (50 mg, 100 mg)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website

npra.gov.my

[Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Ericfil

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Keep tablets in the original package, protected from moisture.

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

- 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

Blue film-coated tablet, round, convex, plain on both sides.

- Ingredients

- Active ingredient:
Sildenafil

- Inactive ingredients:
Microcrystalline cellulose,
Calcium hydrogen phosphate anhydrous,
Croscarmellose sodium,
Magnesium stearate,
Hydroxy propyl methyl cellulose, Titanium dioxide, Lactose monohydrate, Triacetin, FDC Blue No. 2 Aluminium Lake, Purified water.

- MAL Numbers

MAL23076011AZ

Manufacturer

PT Novell Pharmaceutical Laboratories
Jl. Wanaherang No 35, Tlajung Udik, Gunung Putri, Bogor 16962 Indonesia

Product Registration Holder

Averroes Pharmaceutical Sdn. Bhd
03-08-01&03-09-01, Block 3, Presint Alami, Worldwide Business Centre II, Persiaran Akuatik, Seksyen 13, 40100 Shah Alam, Selangor, Malaysia

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