

EUROGRA 50MG & 100MG FILM COATED TABLETS

Sildenafil 50mg & 100mg (as Citrate) Film Coated Tablets

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What EUROGRA is used for

EUROGRA 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 EUROGRA works

EUROGRA 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. EUROGRA will only help you to get an erection if you are sexually stimulated.

Before you use EUROGRA

- 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 EUROGRA.
- 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

EUROGRA 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:

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

- Taking other medicines

EUROGRA tablets may interfere with some medicines. In the event of a medical emergency, you should tell anyone treating your condition that you have taken EUROGRA. Do not take EUROGRA 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 EUROGRA 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 EUROGRA.
- 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.

Taking EUROGRA with food and drink

When EUROGRA is taken with high fat food, it may take a little longer for

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EUROGRA to work.

How to use EUROGRA

- How much to use

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

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

- When to use it

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

- How long to use it

Continue taking EUROGRA 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 EUROGRA.

If EUROGRA 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 EUROGRA 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 EUROGRA 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 EUROGRA.

- Things to be careful of

Driving and using machines
The effect of EUROGRA on the ability to drive and use machinery has not been studied.

EUROGRA can cause dizziness and can affect vision. You should be aware of how you react to

EUROGRA before you drive or use machinery.

Side effects

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

If any of the following happen, stop taking EUROGRA 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.

You may report any side effect of adverse drug reactions Directly to National center for Adverse drug reaction Monitoring by visiting the Website npra.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI))

Storage and disposal of EUROGRA

Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in the original package in order to protect from moisture

Do not use EUROGRA 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.

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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*

EUROGRA 50 mg Film Coated Tablets are Blue, almond shaped, biconvex, film coated tablets, debossed with '50' on one side and plain on other side

EUROGRA 100mg Film Coated Tablets are Blue, almond shaped, biconvex, film coated tablets, debossed with '100' on one side and plain on other side.

The tablets are provided in PVC/Aluminium foil blisters in cartons of 3 X 4 tablets.

Not all pack sizes and strengths may be marketed.

Ingredients

Active ingredient:

Sildenafil

Each tablet contains 50mg /100 mg of sildenafil (as the citrate).

Inactive ingredient:

Microcrystalline cellulose, Dibasic Calcium Phosphate (anhydrous), Croscarmellose sodium, Magnesium stearate, Hypromellose 15cP (E464) Titanium Dioxide (E171) , Lactose Monohydrate ,Triacetin, Indigo Carmine Aluminium Lake (E132).

MAL NO:

MAL*****

Manufacturer:

INTAS PHARMACEUTICALS LIMITED

Plot No. 457, 458 Matoda, Plot No. 191/218P, Chacharwadi Sarkhej Bavla Highway, Ahmedabad, 382 210, INDIA.

Product Registration Holder:

Accord Healthcare Sdn Bhd (1035160 D), Suite 12A-15, Level 12A, Wisma Zelan, No 1 Jalan Tasik Permaisuri 2 , Bandar Tun Razak, 56000 Kuala Lumpur

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