

REVATIO® FILM-COATED TABLET

Sildenafil citrate (20 mg)

What is in this leaflet

1. What REVATIO is used for
2. How REVATIO works
3. Before you use REVATIO
4. How to use REVATIO
5. While you are using it
6. Side Effects
7. Storage and Disposal of REVATIO
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What REVATIO is used for

REVATIO is indicated to treat adults with high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension), to improve exercise capacity.

How REVATIO works

REVATIO belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

REVATIO brings down blood pressure in the lungs by widening the blood vessels in the lungs.

Before you use REVATIO

- When you must not use it

- if you are allergic (hypersensitive) to sildenafil or any of the other ingredients of this medicine (listed in section "Ingredients").
- if you are taking medicines containing nitrates or nitric oxide donors.
- REVATIO can cause a serious increase in the low blood pressure effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- if you have pulmonary hypertension due to abnormality of red blood cells (sickle cell anaemia).
- if you are taking PDE5 inhibitors, including guanylate cyclase stimulators, such as

riociguat.

- if you have recently had a stroke, a heart attack or if you have severe liver disease or very low blood pressure (<90/50 mmHg).
- if you are taking a medicine to treat fungal infections such as ketoconazole or itraconazole or medicines containing ritonavir (for HIV).
- if you have ever had loss of vision because of a problem with blood flow to the nerve in the eye called non-arteritic anterior ischaemic optic neuropathy (NAION).

Pregnancy and breast-feeding

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. REVATIO should not be used during pregnancy unless strictly necessary.

REVATIO should not be given to women of child bearing potential unless using appropriate contraceptive methods.

REVATIO passes into your breast milk at very low levels and would not be expected to harm your baby. It should be given after assessing the mother's clinical need and any side effects on the breast-fed child.

- Before you start to use it

Talk to your doctor before taking REVATIO if you:

- have a severe heart problem.
- have obstruction with the pumping chambers of your heart.
- have low blood pressure.
- lose a large amount of body fluids (dehydration).

This can happen if you are sick with a fever, vomiting, or

diarrhoea.

- have a rare inherited degenerative eye disease (retinitis pigmentosa).
- have cancer of blood cells (leukaemia), cancer of bone marrow (multiple myeloma), or any disease or deformity of the penis.
- currently have a stomach ulcer, a bleeding disorder.
- have children and it is prescribed for your child as the safety and efficacy has not been established in children less than 18 years of age. Long term use is not recommended in children.

Special considerations for individuals with kidney or liver problems

You should tell your doctor if you have kidney or liver problems, as your dose may need to be adjusted.

- Taking other medicines

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 such as nicorandil or nitric oxide donors such as amyl nitrate. These medicines are often given for relief of angina or "chest pain".
- Vitamin E antagonist.
- Therapies for high blood pressure in the lungs (e.g. ambrisentan, iloprost).
- Medicines containing St. John's Wort (herbal medicinal product), carbamazepine, phenytoin and phenobarbital (used to treat epilepsy).
- Blood thinning medicines (for example vasodilators such as prostacyclin beta blocker).
- Medicine to treat fungal infections such as ketoconazole or itraconazole.
- Medicines containing

REVATIO® FILM-COATED TABLET

Sildenafil citrate (20 mg)

erythromycin, clarithromycin, rifampicin, telithromycin (these are antibiotics used to treat certain bacterial infections), ritonavir, saquinavir (for HIV) or nefazodone (for depression), as your dose may need to be adjusted.

- 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 resulting in the lowering of your blood pressure (e.g. dizziness, light headedness).
- Sacubitril/valsartan for the treatment of heart failure

Taking REVATIO with food and drink

You should not drink grapefruit juice while you are being treated with REVATIO.

Revatio may be taken with or without food.

How to use REVATIO

- How much to use

Treatment should only be initiated and monitored by a physician experienced in the treatment of pulmonary arterial hypertension.

For adults, the recommended dose is 20 mg three times a day (taken 6 to 8 hours apart).

- When to use it

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

If you stop taking REVATIO
Suddenly stopping your treatment with REVATIO may lead to your symptoms getting

worse. Do not stop taking REVATIO unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

- If you forget to use it

If you forget to take REVATIO, take a dose as soon as you remember, then continue to take your medicine at the usual times. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

You should not take more medicine than your doctor tells you to.

If you take more medicine than you have been told to take, contact your doctor immediately. Taking more REVATIO than you should, may increase the incidence rates and severities of known side effects.

While you are using it

- Things you must do

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Driving or using machines
REVATIO can cause dizziness and can affect vision. You should be aware of how you might be affected by the medicine before you drive or use machines.

If you experience sudden decrease or loss of vision, **stop taking REVATIO and contact your doctor immediately.**

If you experience a sudden decrease or loss of hearing, **contact your doctor immediately.**

In case of an erection of the penis that persists longer than 4 hours, **contact your doctor immediately.**

Important information about some of the ingredients of REVATIO

Lactose monohydrate is present in the tablet film coat. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

REVATIO 20 mg tablets contain less than 1 mmol sodium (23 mg) per tablet, essentially 'sodium-free'.

Side Effects

Like all medicines, REVATIO can cause side effects, although not everybody gets them.

Side effects which have been reported in men after taking sildenafil with unknown frequency are prolonged and sometimes painful erections.

Below are the side effects reported very commonly (may affect more than 1 in 10 people):

- headache
- flushing
- indigestion
- diarrhoea
- pain in the arms or legs

Side effects reported commonly (may affect less than 1 in 10 people) are:

- infection under the skin
- flu-like symptoms, inflammation of the sinuses

REVATIO® FILM-COATED TABLET

Sildenafil citrate (20 mg)

- reduced number of red blood cells (anaemia)
- fluid retention
- difficulty in sleeping
- anxiety
- migraine
- shaking
- “pins and needles”-like sensation, burning sensation, reduced sense of touch
- bleeding at the back of the eye, effects on vision, blurred vision and light sensitivity
- effects on colour vision, eye irritation, bloodshot eyes/red eyes
- spinning sensation
- inflammation in the airway
- nosebleed, runny nose, cough, stuffy nose
- digestive system inflammation
- heartburn
- piles, abdominal distension
- dry mouth
- hair loss
- redness of the skin, night sweats
- muscle pain
- back pain
- fever

Skin rash and sudden decrease or loss of hearing and decreased blood pressure have also been reported at an unknown frequency (frequency cannot be estimated from the available data).

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

Storage and Disposal of REVATIO

- Storage

Keep this medicine out of the sight and reach of children.

Do not use REVATIO after the expiry date which is stated on the carton or blister strip.

Do not store above 30°C. Store in the original package in order to protect from moisture.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

REVATIO tablets are white, round, biconvex film-coated tablets. The tablets are marked with “VLE” on one side and “RVT 20” on the other. The tablets are provided in blisters packs containing 90 tablets (15 tablets per blister strip) in a carton.

- Ingredients

- Active ingredient:

The active substance is sildenafil. Each tablet contains 20 mg of sildenafil (as the citrate).

- Inactive ingredients:

Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate.

Film coat: hypromellose, titanium dioxide (E171), lactose monohydrate, glycerol triacetate.

- MAL Number:

MAL20071716ACRZ

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Product Registration Holder

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