Sildenafil is a treatment for adult men with impotence. This is when a man cannot get, or cannot keep, firm enough an erection to have satisfactory sexual activity.

**What sildenafil looks like and contents of the pack and other information**

Sildenafil is supplied in the following pack sizes:

- 25mg, 50mg, 100mg film-coated tablets
- 2x24 50mg film-coated tablets (迟释膜衣片)
- 2x24 100mg film-coated tablets (迟释膜衣片)

**Sildenafil contains**

- Sildenafil citrate 25mg, 50mg or 100mg per film-coated tablet
- Other ingredients: lactose (non-vegetarian and vegetarian), colloidal silicon dioxide, magnesium stearate, hydroxypropyl cellulose, triacetin, titanium dioxide (E171), methylene blue, red iron oxide (E172), yellow iron oxide (E177)

Each film-coated tablet contains:

- 25mg of sildenafil (as 25.0mg sildenafil citrate)
- 50mg of sildenafil (as 50.0mg sildenafil citrate)
- 100mg of sildenafil (as 100.0mg sildenafil citrate)

**How to take sildenafil**

1. The treatment of choice for the improvement of impotence
2. If you are taking any of the medicines classified as nitrates and nitric oxide donors, you should not take sildenafil
3. If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)
4. If you have severe heart or liver problems
5. If you have a history of heart attack or stroke
6. If you have a history of any of the following conditions: diabetes, high blood pressure, high cholesterol, heart disease, smoking, obesity, among other medical conditions

**Special considerations for patients with kidney or liver problems**

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

**Children and adolescents**

Sildenafil should not be given to individuals under the age of 18.

**Other medicines and sildenafil**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Sildenafil film-coated tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor or pharmacist that you have taken sildenafil and when you did. Do not take sildenafil with other medicines unless your doctor tells you that you can.

You should not take sildenafil if you are taking medicines called nitrates as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or “chest pain”).

You should not take sildenafil if you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a dangerous fall in your blood pressure.

You should not take sildenafil if you are using any of the medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25mg) of sildenafil.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking sildenafil with alpha-blockers. This is most likely to happen within 4 hours after taking sildenafil. In order to reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start sildenafil. Your doctor may start you on a lower dose (25mg) of sildenafil.

Sildenafil with food, drink and alcohol

Sildenafil can be taken with or without food. However, you may find that sildenafil takes longer to start working if you take it with a heavy meal.

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

Pregnancy, breast feeding and fertility

Sildenafil is not indicated for use by women.

**Driving and using machines**

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

**Sildenafil contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking sildenafil.

**How to take sildenafil**

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 50mg. You should not take sildenafil more than once a day.

Do not take sildenafil film-coated tablets in combination with sildenafil containing ondansetron tablets.

You should take sildenafil about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you feel that the effect of sildenafil is too strong or too weak, talk to your doctor or pharmacist.

Sildenafil will only help you to get an erection if you are sexually stimulated. The amount of time sildenafil takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that sildenafil takes longer to work if you take it with a heavy meal.
4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. The side effects reported in association with the use of sildenafil are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking sildenafil and seek medical help immediately:
- An allergic reaction (this occurs rarely)
- Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pain (this occurs uncommonly): If this occurs during or after intercourse. Get in a semi-sitting position and try to relax.
- Do not use nitrites to treat your chest pain.
- Prolonged and sometimes painful erections (frequency unknown). If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision (frequency unknown). Serious side reactions (frequency unknown). Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits (frequency unknown)

Other side effects:

Very common (may affect more than 1 in 10 people): headache.

Common (may affect up to 1 in 10 people): facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision), stuffy nose, dizziness.

Uncommon (may affect up to 1 in 100 people): vomiting, skin rash, bleeding at the back of the eye, eye irritation, bloodshot eyes/red eyes, eye pain, double vision, abnormal sensation in the eye, watery eyes, pounding heartbeat, rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, penile bleeding, presence of blood in semen and/or urine, chest pain and feeling tired.

Rare (may affect up to 1 in 1000 people): high blood pressure, low blood pressure, fainting, stroke, heart attack, irregular heartbeat, nosebleed and sudden decrease or loss of hearing.

Not known (frequency cannot be estimated from the available data): Additional side effects reported from post-marketing experience: Unstable angina (a heart condition), sudden death, temporary decreased blood flow to parts of the brain. Most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to sildenafil.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store sildenafil

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton, label and blister after ‘EXP’. The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What sildenafil contains

The active substance is sildenafil.

Each 25mg film-coated tablet contains 25mg of sildenafil (as 35.12mg sildenafil citrate).

Each 50mg film-coated tablet contains 50mg of sildenafil (as 70.24mg sildenafil citrate).

Each 100mg film-coated tablet contains 100mg of sildenafil (as 140.48mg sildenafil citrate).

The other ingredients are:
- Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate.
- Tablet coating: lactose monohydrate, hypromellose, titanium dioxide (E171), tartrazine, indigo carmine aluminium lake (E132).

What sildenafil looks like and contents of the pack

Sildenafil 25mg film-coated tablet

Blue coloured round, biconvex, film-coated tablets debossed with ‘125’ on one side and ‘J’ on the other side.

Sildenafil 50mg film-coated tablet

Blue coloured round, scored biconvex, film-coated tablets debossed with ‘125’ on one side and ‘J’ on the other side with the score line. The tablet can be divided into equal doses.

Sildenafil 100mg film-coated tablet

Blue coloured round, biconvex, scored film-coated tablets debossed with ‘125’ on one side and ‘J’ on the other side with the score line. The tablet can be divided into equal doses.

Sildenafil is supplied in the following pack sizes:

Sildenafil 25 mg film-coated tablets

PVC/Aluminium foil blisters in cartons of 1, 2, 4, 8, 12 or 24 film-coated tablets.

Sildenafil 50mg film-coated tablets

PVC/Aluminium foil blisters in cartons of 1, 2, 4, 8, 12, 24, 2x24 film-coated tablets.

Sildenafil 100mg film-coated tablets

PVC/Aluminium foil blisters in cartons of 1, 2, 4, 8, 12, 24, 2x24 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

Manufacturer

Pharmacia Healthcare Ltd.

KW02A Kordin Industrial Park, Paola, PTLA 3000, Malta

Or

S.C. Zentiva S.A.

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PRODUCT NAME: Sildenafil

DOSEAGE: 25/50/100Mg

PHARM. FORM: Comprimates

ARTWORK VERSION: V1

ARTWORK CREATION DATE: 28/10/2015

PLANT NAME: BUCHAREST

ARTWORK BY: L. FLOREA

CHANGE CONTROL: new pack size 2x24 bundle

FORMAT (size): 148 x 420 mm

MATERIAL: According to tests

LAETUS (optical code/pharma code): (3100)

SERIALIZATION: NO

FONT + MIN. SIZE: Helvetica, 9 pt

NUMBER OF COLORS: 1

BLACK