Package leaflet: Information for the patient

Entranin 50 mg, kauwtabletten
Entranin 100 mg, kauwtabletten

Sildenafil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

1. What [Product name] is and what it is used for

[Product name] contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) 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. [Product name] will only help you to get an erection if you are sexually stimulated.

[Product name] 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.

2. What you need to know before you take [Product name]

Do not take [Product name]
- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- 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.
- If you 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 sildenafil have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as *retinitis pigmentosa*).

- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [Product name]
- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have a deformity of your penis or Peyronie's Disease.
- 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 currently have a stomach ulcer, or bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking [Product name] and contact your doctor immediately.

You should not use [Product name] with any other oral or local treatments for erectile dysfunction.

You should not use [Product name] with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take [Product name] if you do not have erectile dysfunction.

You should not take [Product name] if you are a woman.

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
[Product name] should not be given to individuals under the age of 18.

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

[Product name] chewable 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, pharmacist or nurse that you have taken [Product name] and when you did. Do not take [Product name] with other medicines unless your doctor tells you that you can.

You should not take [Product name] 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, pharmacist or nurse 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 [Product name] 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.

Tell your doctor or pharmacist if you are already taking riociguat.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of [Product name]*.

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 [Product name] with alpha-blockers. This is most likely to happen within 4 hours after taking [Product name]. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start [Product name]. Your doctor may start you on a lower dose (25 mg) of [Product name].

Tell your doctor or pharmacist if you are taking, have recently taken or might take medicines containing sacubitril/valsartan, used to treat heart failure.

*The dose of 25 mg is not available with this product. For doses not achievable with [Product name] chewable tablets, other brands of sildenafil are available and can be used.

[Product name] with food, drink and alcohol
[Product name] can be taken with or without food. However, you may find that [Product name] 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 [Product name].

Pregnancy, breast-feeding and fertility
[Product name] is not indicated for use by women.

Driving and using machines
[Product name] can cause dizziness and can affect vision. You should be aware of how you react to [Product name] before you drive or use machinery.

[Product name] contains aspartame, lactose and sodium
[Product name] contains 4.30 mg aspartame in each tablet. [Product name] contains 8.60 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
[Product name] contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take [Product name]

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

The recommended starting dose is 50 mg.

You should not take [Product name] more than once a day.

You should take [Product name] about one hour before you plan to have sex. The tablet should be chewed whole.

If you feel that the effect of [Product name] is too strong or too weak, talk to your doctor or pharmacist.

[Product name] will only help you to get an erection if you are sexually stimulated. The amount of time [Product name] takes to work varies from person to person, but it normally takes between half an

hour and one hour. You may find that [Product name] takes longer to work if you take it with a heavy meal.

If [Product name] 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 take more [Product name] than you should
You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

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 medicine, ask your doctor, pharmacist or nurse.

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 [Product name] and seek medical help immediately:

- An allergic reaction- this occurs uncommonly (may affect up to 1 in 100 people)
  Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

- Chest pains- this occurs uncommonly
  If this occurs during or after intercourse:
  - Get in a semi-sitting position and try to relax.
  - **Do not use nitrates** to treat your chest pain.

- Prolonged and sometimes painful erections- this occurs rarely (may affect up to 1 in 1 000 people). 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- this occurs rarely
- Serious skin reactions- this occurs rarely
  Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits- this occurs rarely

Other side effects:

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

Common (may affect up to 1 in 10 people):
Nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

Uncommon (may affect up to 1 in 100 people):

Vomiting, skin rash, eye irritation, bloodshot eyes /red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

Rare (may affect up to 1 in 1 000 people):
Fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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

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

Store in the original container in order to protect from light.

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 [Product name] contains

- The active substance is sildenafil.
  Each tablet contains 50 mg or 100 mg sildenafil (as citrate salt).
- The other ingredients are: polacrilin potassium, silica colloidal anhydrous, lactose monohydrate, povidone K-30 , aspartame (E951), croscarmellose sodium, peppermint flavour (consisting of: maltodextrin, modified starch (E1450) and peppermint oil), magnesium stearate, potassium hydroxide (for pH adjustment) or hydrochloric acid (for pH adjustment).

What [Product name] looks like and contents of the pack

White, triangular, biconvex tablets, embossed with “50” on one side, with a diameter of 8.8 x 8.6±0.2 mm.
White, triangular, biconvex tablets, embossed with “100” on one side, with a diameter of 11.8 x 11.6±0.2 mm.

The tablets are provided in blister packs of 1, 2, 4, 8 or 12 chewable tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Labormed Pharma S.A.
Theodor Pallady, NR. 44B, 032266 Bucharest
Romania

Manufacturer
Genepharm S.A.
18th km Marathon Avenue,
15351 Pallini
Griekenland

Pharma Pack Hungary Kft..
Vasút utca 13., Budaörs, 2040 7
Hongarije

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000
Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Netherlands:	Entranin 50 mg kauwtabletten
	Entranin 100 mg kauwtabletten
Romania:	Entranin 50 mg comprimate masticabile
	Entranin 100 mg comprimate masticabile

Deze bijsluiter is voor het laatst goedgekeurd in september 2022