

Package leaflet: Information for the user
Hezkue 12.5mg/actuation, oral suspension
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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Hezkue is and what is it used for
2. What you need to know before you take Hezkue
3. How to take Hezkue
4. Possible side effects
5. How to store Hezkue
6. Contents of the pack and other information

1. What Hezkue is and what is it used for

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

Hezkue 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 Hezkue

Do not take Hezkue:

- 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 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).
- 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 secondary to blood clots). PDE5 inhibitors, such as Hezkue has been shown to increase the hypotensive effects of this medicine. If you are taking Riociguat or are unsure tell your doctor.

Warnings and precautions

Check with your doctor before taking Hezkue:

- 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 a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Hezkue and contact your doctor immediately.

You should not use Hezkue with any other oral or local treatments for erectile dysfunction.

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

You should not take Hezkue if you do not have erectile dysfunction.

You should not take Hezkue 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

Do not give this medicine to children and adolescents under 18 years of age.

Other medicines and Hezkue

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

Hezkue 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 Hezkue and when you did. Do not take Hezkue with other medicines unless your doctor tells you that you can.

You should not take Hezkue 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 Hezkue 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 (1 ml is equivalent to 25 mg of sildenafil) of Hezkue.

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 Hezkue with alpha-blockers. This is most likely to happen within 4 hours after taking Hezkue. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start Hezkue. Your doctor may start you on a lower dose (1 ml is equivalent to 25 mg of sildenafil) of Hezkue.

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

Hezkue with food and drink and alcohol

Hezkue can be taken with or without food. However, you may find that Hezkue 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 this medicine.

Pregnancy and breast-feeding

Hezkue is not indicated for use in women.

Driving and using machines

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

Hezkue contains sodium benzoate

This medicinal product contains 1 mg of sodium benzoate per ml of suspension.

Patients on low sodium diets can be informed that this medicinal product is essentially ‘sodium-free’.

3. How to take Hezkue

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

The recommended dose is 2 ml equivalent to 50 mg (4 pumps). Each press of the dosing pump releases 0.5 ml of suspension containing 12.5 mg of sildenafil.

If this medicine 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.

Your doctor may then recommend a decrease or increase of the dose to 1 ml of the suspension equivalent to 25 mg (2 pumps), or 4 ml of suspension equivalent to 100 mg (8 pumps).

You should take Hezkue about an hour before you plan to have sex. Hezkue should not be taken more than once a day.

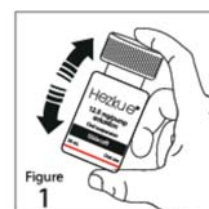
Do not take Hezkue together with other medications that contain sildenafil.

Method of administration

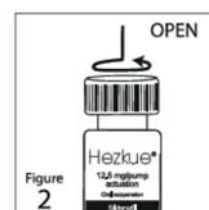
This medication is to be administered orally. **Do not administer this medicine via the nose and do not apply this medicine on the skin.** Your doctor will prescribe you the correct number of doses you need. For a correct administration, please follow the Instructions for Use. Always use the pump supplied with the pack.

Instructions for use

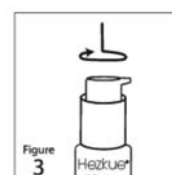
Shake the bottle vigorously for approximately 20 seconds to ensure that the medicine is mixed in the bottle before each use (Fig 1).



Remove the child-resistant screw cap by pushing it down firmly and turning it anticlockwise. (Fig 2)



Place the dosage pump on top of the bottle, sliding the plastic tube carefully into the liquid in the bottle. Hold the dosing pump onto the neck of the bottle and screw clockwise until it is firmly attached to the bottle. (Fig 3)



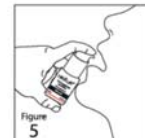
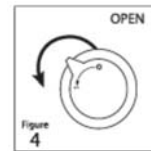
Turn the nozzle on the dosing pump to the open position. (Fig 4)

Before every use (including first-time use):

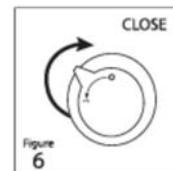
Activate the pump three times to prepare (prime) the dosage pump, discard any product released during this activation into an absorbent material. The pump is now ready to be used and each metered spray delivers an average of 12.5 mg of sildenafil.

A failure in this priming process may lead to a lower dose when used.

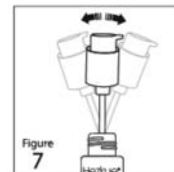
Tilt your head back a little. Open your mouth and put the bottle next to your chin (see picture). Press the dosage pump as many times as required, according to the dose prescribed by your doctor. Apply the suspension onto the tongue and swallow the suspension immediately with saliva. Avoid direct contact between the end of the dosage pump and the inside of the mouth and tongue. (Fig 5)



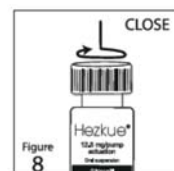
Turn the nozzle on the dosage pump to the closed position. (Fig 6)



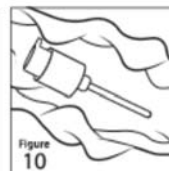
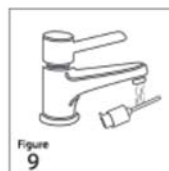
Remove the pump from the bottle unscrewing anticlockwise. Tap the plastic tube against the internal wall of the bottle to remove any excess liquid. (Fig 7)



Put the child resistant screw cap back on the bottle and turn clockwise to close it immediately after each use. (Fig 8)



Wash the dosage pump thoroughly with water. Ensure no product or water remains in the pump by activating the pump several times into an absorbent material. Allow the pump to dry thoroughly before the next use. (Fig 9 & 10)



NOTE FOR PATIENTS – Hezkue requires priming before each dose and washing of the dosing pump after each use. Therefore, a small amount of product is discarded with each use. The approximate volume of Hezkue that is used is 20 ml in each 30 ml bottle.

Once the volume of the product in the bottle goes below the red line (marked on the bottom of the bottle), stop using Hezkue and discard.

If you take more Hezkue than you should

You may experience an increase in side effects and their severity.

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

Contact your doctor if you take more doses 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.

Side effects with Hezkue may include:

- Allergic reaction - this occurs infrequently (may affect up to 1 in 100 people). Symptoms include sudden wheezing, shortness of breath or dizziness, swelling of the eyelids, face, lips, or throat. Get medical help **immediately** if you get any of these symptoms.
- Chest pains - this occurs infrequently (may affect up to 1 in 100 people). If they appear during or after sexual intercourse:
 - Get into a semi-sitting position and try to relax.
 - Do not use nitrates to treat chest pain.
 - Contact your doctor **immediately**.
- Prolonged and sometimes painful erections - this occurs rarely (may affect up to 1 in 1,000 people). If you have an erection that lasts more than 4 hours, you should contact your doctor **immediately**.
- A sudden decrease or loss of vision - this occurs rarely (may affect up to 1 in 1,000 people). If this happens contact your doctor **immediately**
- Serious skin reactions - this occurs rarely (may affect up to 1 in 1,000 people). If you experience symptoms which can include severe peeling and swelling of the skin, buccal blisters, bumps on the genitals and around the eyes, and fever. contact your doctor **immediately**.
- Seizures or fits - this occurs rarely (may affect up to 1 in 1,000 people). If this happens contact your doctor **immediately**.

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
- flushing (symptoms include a feeling of sudden warmth in the upper body)
- indigestion
- abnormal colour perception

- blurred vision
- visual impairment
- nasal congestion
- dizziness

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

- vomiting
- skin rash
- eye irritation, eye discharge / red eyes, eye pain
- vision of flashing lights, visual clarity, sensitivity to light, watery eyes
- palpitations
- fast heart rate
- high blood pressure
- low blood pressure
- muscle pain
- feeling drowsy
- reduced touch sensation
- vertigo
- ringing in the ears
- dry mouth
- blocked or congested sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing, and nasal congestion)
- upper abdominal pain
- gastroesophageal reflux disease (symptoms include heartburn)
- blood in urine
- pain in arms or legs
- nosebleed
- feeling of heat
- feeling of tiredness

Rare (may affect up to 1 in 1,000 people):

- fainting
- stroke
- heart attack
- irregular heartbeat
- temporary decrease in blood flow to some parts of the brain
- feeling of tightness in the throat
- numbness in the mouth
- bleeding in the back of the eye
- double vision, decreased visual acuity
- abnormal sensation in the eye, swelling of the eye or eyelid
- small particles or spots in the vision, vision of halos around lights
- dilation of the eye pupil, change colour of the whites of the eye
- bleeding from the penis

- presence of blood in the semen
- dry nose, swelling inside the nose
- feeling of irritability
- 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

HPRA Pharmacovigilance.
 Earlsfort Terrace.
 IRL - Dublin 2.
 Tel: +353 1 6764971.
 Fax: +353 1 6762517.
 Website: www.hpra.ie
 e-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Hezkue

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

Do not use Hezkue after the expiry date which is stated on the carton and bottle as “EXP”. The expiry date refers to the last day of that month. The expiry date after first opening of the bottle is 10 months.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Hezkue contains

The active substance is sildenafil.

Each ml (corresponds to TWO pumps) of suspension contains 25 mg of sildenafil (35.1mg as citrate).

The other ingredients are:

sodium benzoate, anhydrous citric acid, sucralose, acesulfame potassium, hypromellose, xanthan gum, peppermint flavour, masking flavour, purified water

What Hezkue looks like and contents of the pack

Hezkue is White to off White with a mint aroma flavour oral suspension

The primary packaging material of the product Hezkue consists of high-density polyethylene (HDPE) translucent bottles with 30 ml of drug product, closed with a high-density polyethylene (HDPE) child-resistant cap and a metering pump of 0.5ml per pump as the administration device.

Manufacturer

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