

The Pharmacy Checklist

This information pack has been created to help you determine if your patient is suitable for Eropid (Sildenafil). Within this pack is an optional checklist below and overleaf, that you may use to help assess the suitability of your patient. **In ALL cases your professional judgement should be used to decide when and how to use it.** Further information and copies of this checklist can be found at www.somexpharma.com

Who Eropid is for:

Eropid is solely intended for men 18 years and older who are experiencing erectile dysfunction (ED), also known as impotence; this is the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance. It's important to confirm if the patient's already receiving treatment for the condition, those who are currently prescribed 50 mg of sildenafil can be supplied this product if the patient meets the criteria for pharmacy supply, given that they do not take more than 50 mg daily. Remind the patient to follow up with his doctor within the first 6 months of use. Should the patient be using a different dose of sildenafil or another ED treatment, they should be referred to their doctor.

Causes of erectile dysfunction:

Erectile dysfunction has multiple causes which should be considered and support should be offered to patients, regardless of suitability for this product. This may include undiagnosed depression, anxiety, stress or worry. Other causes include side effects of medications such as: diuretics, anti-hypertensives, corticosteroids, anticonvulsants and recreational drugs. Patients should be made aware of other risk factors that include excessive drinking, smoking, obesity and a lack of exercise.

Suitability checklist:

These are questions to ask your patients, in order to determine their suitability.

If the patient answers yes to any of the following, do NOT supply the product and refer the patient to their doctor.

Please put Yes / No into the respective check boxes

Y N 1. Check the patient's CARDIOVASCULAR (CV) HEALTH by asking the following:

- Have you been advised by your doctor that you are not fit enough for any physical or sexual activity?
- Do you feel very breathless or experience chest pain with light/moderate physical activity e.g. walking briskly for twenty minutes or climbing two flights of stairs
- Have you had a heart attack or stroke within the last six months?
- Do you have any other heart problems or are under a doctor's care for any of the following?
 - Low blood pressure or uncontrolled high blood pressure
 - Unstable angina (chest pain), irregular heartbeat or palpitations (arrhythmia)
 - A problem with one of the valves in your heart (valvular heart disease)
 - A problem where your heart muscle becomes inflamed and doesn't work as well as it should (cardiomyopathy)
 - Heart problems causing blood flow issues (e.g. left ventricular outflow obstruction, aortic narrowing) or severe cardiac failure

Y N 2. Check the patient's CURRENT MEDICATIONS for interactions by asking the following:

- Are you taking any nitrates for chest pain? (nicorandil or other nitric oxide donors e.g. glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate)
- Are you using drugs called 'poppers' (amyl nitrite) for recreational purposes?
- Are you taking riociguat or other guanylate cyclase stimulators for lung problems?
- Are you taking ritonavir (for HIV infection)?
- Are you taking any CYP3A4 inhibitors e.g. saquinavir (to treat HIV infection), cimetidine (for heartburn), itraconazole or ketoconazole (to treat fungal infections), erythromycin or rifampicin (antibiotics) or diltiazem (for high blood pressure)?
- Are you taking any alpha-blockers, such as alfuzosin, doxazosin or tamsulosin, which are medicines used to treat urinary problems due to an enlarged prostate (benign prostatic hyperplasia) or occasionally to treat high blood pressure?

Y N 3. Check for OTHER CONTRAINDICATIONS:

- Do you have Peyronie's disease or any other disease, injury or deformation of the penis?
- Have you ever had loss of vision because of damage to the optic nerve (e.g. non-arteric anterior ischaemic optic neuropathy [NAION]) or have an inherited eye disease (e.g. retinitis pigmentosa)?
- Do you have intolerance to galactose, Lapp lactase deficiency or glucose-galactose malabsorption?
- Do you have previously diagnosed hepatic (liver) disease (including liver cirrhosis), or severe renal (kidney) impairment?
- Do you have any of the following: sickle cell anaemia, multiple myeloma or leukaemia?
- Do you have any bleeding issues (e.g. haemophilia) or any active stomach ulcers?

Your pharmacist has supplied you with Eropid today for your personal use.

Please ensure that you make an appointment to see your GP within 6 months of the date of receiving Eropid (see date on reverse)

You have not been provided with Eropid (sildenafil) for ED today, as it may not be suitable for you to take without consulting a doctor first.

You should go to see your doctor as soon as you can to discuss other suitable options, please present this slip to your GP

Counselling Points for Patients and Other Information

Please follow these points to ensure that your patient is counselled appropriately, regardless of product supply:

Advice for patients who have not been supplied Eropid:

Should a patient not have been supplied Eropid because of their cardiovascular health, interacting medicines or other concerns, they must be told to see their GP as soon as they can within six months.

Advice for patients who have been supplied Eropid:

- Eropid is only intended for men 18 years and older who have erectile dysfunction and others who don't, won't benefit from using this product
- Take one tablet approximately 1 hour before planning to have sexual intercourse, Eropid can start working within 30 minutes. Sexual stimulation (foreplay) and arousal is still required to attain an erection.
- Take Eropid with or without food, but Eropid can take longer to work after a high-fat meal
- Avoid taking with grapefruit or grapefruit juice, as it may affect the way the medicine works
- Large amounts of alcohol should be avoided, as it can increase the risk and incidence of side effects
- The maximum dose frequency is one 50 mg tablet per day
- Eropid may need to be taken a number of times on different occasions, before they can achieve a penile erection sufficient for satisfactory sexual activity. If after several failed attempts in achieving an erection sufficient for satisfactory sexual activity, they should consult a doctor
- Patients should be warned not to take any medicines called nitrates or nitric oxide donors, (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, for the relief of chest pain or heart failure or amyl nitrite also known as "poppers", nicorandil or sodium nitroprusside), as the combination may lead to a dangerous fall in blood pressure;
- Patients should notify their doctor and pharmacists that they have started taking Eropid, especially if they are started on any new medicines
- Patients may experience some normal side effects including, but not limited to: headache, facial flushing, hot flush, dyspepsia, nausea, nasal congestion, dizziness, visual disturbance, cyanopsia (blue-tinted vision) and blurred vision – should any of these become a concern, advise the patient to talk with a pharmacist or doctor
- **Should any of the following serious side effects occur, the patient should stop taking Eropid and seek immediate medical attention:**
 - o Chest pains. If these occur before, during or after intercourse get into a semi-sitting position and try to relax. Nitrates must NOT be used to treat chest pain.
 - o A persistent and sometimes painful erection lasting longer than 4 hours
 - o A sudden decrease or loss of vision
 - o An allergic reaction - symptoms include: sudden wheeziness, difficulty breathing or dizziness, swelling of the face, eyelids, lips or throat, peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever
 - o Seizures or fits
 - o Patient should inform their doctor if they have started taking Eropid.
 - o Eropid contains tartrazine: May cause allergic reactions as it contains Tartrazine (E-102). It can worsen asthma

Side effects can be reported by patients or pharmacists via the Yellow Card scheme at www.mhra.gov.uk/yellowcard/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

The tear off slip should be filled in and provided to the man to facilitate discussion with their doctor.

Follow up advice for all patients:

- Erectile dysfunction can be associated with a number of contributing conditions (e.g. hypertension, hypercholesterolaemia or cardiovascular disease. As a result, ALL patients with erectile dysfunction should be advised to consult their doctor within six months for a clinical review of potential underlying conditions and risk factors associated with erectile dysfunction
- Provide appropriate advice on lifestyle factors and general healthy living, including:
 - o Losing weight, if obese
 - o Giving up smoking, recommend smoking cessation services
 - o Cutting back on alcohol and/or recreational drug use
 - o Exercising regularly
 - o Reducing stress
 - o Eating a healthy diet
- Also check if the patient is buying products from unregulated sources and explain the importance of the products not having been tested for their safety or effectiveness, may not contain the ingredients listed on their labels and therefore are potentially dangerous, unlike products sourced from a pharmacy and obtained via a prescription from the doctor.

If the patient has previously been supplied with Eropid, they should be asked if anything has changed with respect to their health status or medicines usage, there is no need to repeat the checklist again.

Give the patient a reminder to follow up with their doctor within the first 6 months of use.

If any factors have changed, the suitability checklist should be reviewed again.

The tear-off slip below can be provided to the patient to present for a repeat supply:

<p>Dear Doctor,</p> <p>Please can you review this patient in relation to erectile dysfunction. We had a discussion in my pharmacy, but they were not suitable for Eropid (sildenafil) due to their cardiovascular health/interacting medicines/ other condition:</p> <p>.....</p> <p>Pharmacist signature:Date:</p>	<p>PHARMACY STAMP</p>	<p>Please keep this slip and present to the pharmacist when you next wish to purchase Eropid</p> <p>Before resupply, your pharmacist will need to assess you to ensure that there have been no changes in your health or medications since the last supply.</p> <p>Pharmacist signature:Date:</p>	<p>PHARMACY STAMP</p>
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