

Package leaflet: Information for the patient
DEPONIT® 5 mg/24 h transdermal patch
Glyceryl trinitrate 18.7 mg

Read all of this leaflet carefully before you start using 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 Deponit 5 is and what it is used for
2. What you need to know before you use Deponit 5
3. How to use Deponit 5
4. Possible side effects
5. How to store Deponit 5
6. Contents of the pack and other information

1. What Deponit 5 is and what it is used for

Deponit 5 belongs to a group of medicines called 'nitrates'. These are used to widen your blood vessels and reduce the workload of your heart.

Deponit 5 is used to prevent angina pectoris. Angina attacks feel like a tight pain in your chest, neck or arm and are a sign that your heart is not getting enough oxygen for the amount of work it is doing.

2. What you need to know before you use Deponit 5

Do not use Deponit 5:

- If you are allergic to glyceryl trinitrate, to other nitro compounds or to any of the other ingredients of this medicine (listed in section 6)
- If you are taking medicines for failure to achieve an erection such as sildenafil or any other phosphodiesterase inhibitors. Using Deponit 5 with these medicines could cause a severe drop in blood pressure and could lead to collapse and unconsciousness, and may be fatal
- If you have a condition in which your heart does not pump enough blood around your body due to obstruction of the arteries in the heart as in a condition called aortic or mitral stenosis.
- If you suffer from a heart condition which is associated with low blood pressure leading to shock.
- If you suffer from low blood pressure
- If you suffer from low blood volume
- If you suffer from anaemia (low iron levels in your blood)
- If you have an eye disease called glaucoma
- If you have a heart valve disorder

- If you suffer from inflammation of the heart lining
- If you suffer from increased fluid around the heart (cardiac tamponade)
- If you suffer from a heart condition called hypertrophic obstructive cardiomyopathy
- If you have ever had a serious head injury, cerebral haemorrhage (bleeding in the brain) or a disease which is accompanied by increased pressure on the brain
- If you have an acute angina attack. Your doctor will give you a different medicine such as a GTN spray for this.
- If you are using riociguat, a medicine used in treating pulmonary hypertension

Warnings and precautions

Talk to your doctor or pharmacist before using Deponit 5:

- If you have an underactive thyroid gland
- If you have any diseases of the lungs, liver or kidneys
- If you have recently had a heart attack or you suffer from heart failure
- If you suffer from hypoxaemia (insufficient oxygen in your blood) due to lung disease, heart failure or severe anaemia (low haemoglobin)
- If you have hypothermia (very low body temperature)
- If you are malnourished (severely underfed)
- If you have had a heart attack
- If you have a condition in which there is insufficient blood flow to the brain (cerebral ischaemia)

Other medicines and Deponit 5

- **Do not take Deponit 5 with medicines for failure to achieve an erection such as phosphodiesterase type-5 inhibitors (e.g. sildenafil, tadalafil, or vardenafil). Using Deponit 5 with these medicines could cause a severe drop in blood pressure and could lead to collapse and unconsciousness, and may be fatal**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- Medicines which are used to treat angina, heart failure, or an irregular heartbeat. A blood condition (methaemoglobinaemia) can occur when other nitrate treatments are given at the same time. This can result in breathing problems, anxiety, loss of consciousness and heart attack.
- Medicines which reduce blood pressure (e.g., beta-blockers, calcium channel blockers, vasodilators, ACE inhibitors, monoamine oxidase inhibitors)
- Diuretics (water tablets)
- Tricyclic antidepressants (used to treat depression)
- Neuroleptics (used to treat anxiety)
- Dihydroergotamine (used to treat migraine)
- Amifostine (drug used along with anticancer drugs) and aspirin should not be taken together with Deponit as they increase the blood pressure lowering effect of Deponit 5
- Sapropterine (Tetrahydrobiopterine, BH4)
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Riociguat (used in treating pulmonary hypertension)
- Any other medicine, including medicines obtained without a prescription

If any of the above applies to you, do not take Deponit 5. Talk to your doctor.

Deponit 5 with alcohol

Do not drink alcohol whilst using Deponit 5 as it can cause your blood pressure to drop too much. This may make you may feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There is data that nitrates are excreted in breast milk and may cause methemoglobinaemia in infants. It is not known how much nitroglycerin passes into human breast milk. A risk to the breastfed child cannot be excluded.

Driving and using machines

Deponit 5 may make you feel dizzy and tired. If this happens to you, do not drive a vehicle or operate machinery. These effects are increased in combination with alcohol.

3. How to use Deponit 5

Always use Deponit 5 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Use in children

Deponit 5 is not suitable for children.

Adults and the Elderly

- Normally one patch per day is enough
- Your doctor may increase this to two patches depending on how you respond to the medicine
- At the start of your treatment, put on a patch in the morning
- Remove the patch before you go to bed
- You must have 10 to 12 hours each day without a patch on. This will prevent you from becoming tolerant to the medicine. If you do this, it will ensure the treatment remains effective
- Each morning put on a new patch.

When applying the patch, you should always:

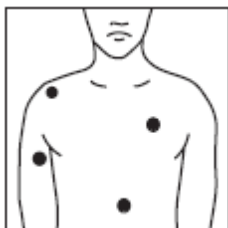
- **Place the new patch on a different area of skin**
- **Allow several days to pass before applying a fresh patch to the same area of skin.**

Things to remember:

- Do not stretch the skin when putting a patch on
- Do not put the patch on a cut or reddened area of skin
- Do not pull the patch off the skin and then stick it back on again.

How and where to apply the patch

- Choose a smooth area of skin to apply the patch. The area should be hairless, to ensure good contact of the patch with the skin. The chest, upper abdomen, upper arm, shoulder or thigh are suitable.



- Your hands and the skin where you will apply the patch should be clean and dry. Do not use powder or moisturiser.
- Tear open the wrapper across the top, take out the patch and hold it with the writing facing away from you.
- Fold the patch along the S-shaped cut so the sides of the backing come apart.
- Hold the patch on one side and peel off the backing on the other side to expose the sticky patch. Place the sticky side of the patch directly onto the skin.
- Peel off the remainder of the backing and press down firmly with the palm of your hand.

If you use more Deponit 5 than you should

If you accidentally use more Deponit 5 than you should, remove the patches straight away and immediately go to your doctor or the nearest hospital casualty department. However, it should be noted that, with the transdermal mode of delivery, an overdose of glyceryl trinitrate is unlikely to occur.

If you use more Deponit 5 than you should, you may have a fall in blood pressure. This may make you feel dizzy, weak and light-headed on standing. You may also experience paleness, sweat a lot, have a weak pulse, rapid heart beats (tachycardia), headache, feel sick or be sick, or experience methaemoglobinaemia (accumulation in blood of methaemoglobin, a form of haemoglobin that can not carry oxygen) This may cause purple colouration of the skin and mucous membranes, rapid breathing, anxiety, and could cause a coma or collapse and require immediate resuscitation. In severe cases of overdose, you may get an increase of the pressure of the fluid around the brain.

If you forget to use Deponit 5

- If you forget to change your patch: Take the old one off and put a new one on as soon as you remember, then carry on as before.
- If you forget to apply a patch: Put a new one on as soon as possible, then carry on as before.

Do not take a double dose to make up for a forgotten dose.

If you stop using Deponit 5

Do not stop using Deponit 5 even if you feel better. If you stop taking your medicine, your condition may get worse. Keep using Deponit 5 until your doctor tells you to stop.

If your doctor thinks you should stop taking Deponit 5, your dose will gradually be reduced. Also, if you are being transferred to another treatment, your dose will be gradually reduced or withdrawn, and the overlapping treatment will be started.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop using Deponit 5 and seek immediate medical help if you have an allergic reaction. This includes any of the following symptoms:

- **Sudden wheeziness**
- **Difficulties in breathing**
- **Swelling of your eyelids, face or lips**
- **Rash or itching especially those covering your whole body.**

Very common side effects (may affect more than 1 in 10 people)

- Headaches at the start of treatment. These may be dose-dependent (stronger with increased dosage of Deponit) and usually disappear after a few days of continuing to use the patches. If necessary, you can take mild painkillers, e.g., paracetamol.

Common side effects (may affect up to 1 in 10 people)

- Sleepiness
- Feeling weak
- Rapid heart beat
- Dizziness
- Low blood pressure (hypotension) and light-headedness upon standing up.

These may occur especially at the start of treatment or when the dosage is increased.

Uncommon side effects (may affect up to 1 in 100 people)

- Worsening angina (tight pain in the chest, neck or arm area)
- Collapse, sometimes accompanied by slow, abnormal heart rate and fainting
- Feeling sick or vomiting
- Allergic skin rashes, which may be severe
- A slight reddening, slight itching or burning sensation on the skin where you have applied the patch. This usually disappears after the patch has been removed. Be sure to put your patch in a different place each day to prevent irritation.

Very rare side effects (may affect up to 1 in 10,000 people)

- Heartburn.

Not known frequency (it cannot be estimated from the available data)

- Palpitations
- Heart rate increased
- Flushing
- Low blood pressure
- Rash, including generalised rash
- Exfoliative dermatitis (serious illness with widespread redness of the skin, accompanied by scaling, peeling, and flaking of the skin, and may include itching and hair loss).

Severe decreases in blood pressure have been reported for drugs in the same class as Deponit and may include nausea, vomiting, restlessness, pallor and excessive sweating.

During the treatment with these patches, you may also suffer with increased chest pain due to a lack of oxygen to the heart muscle and areas around the chest.

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 Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Deponit 5

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

Do not use Deponit 5 after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away 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 Deponit 5 contains

- The active substance is glyceryl trinitrate. Each transdermal patch contains 18.7 mg of glyceryl trinitrate.
- The other ingredients are: acrylate/vinyl acetate copolymer (adhesive matrix); polypropylene (backing foil); and polyethylene or polyethylene terephthalate (siliconised release liner).

What Deponit 5 looks like and contents of the pack

Deponit 5 is a white, translucent square patch with round corners. It has “Deponit 5” marked on the outer face. Each patch is supplied in a foil pouch. There are 28 patches in a box.

Marketing Authorisation Holder

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If this leaflet is difficult to read and you would like it in a different format, please contact

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