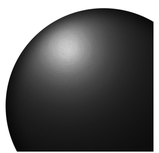
deponit® NT 5 mg

GLYCERYL TRINITRATE



4010991 11/80 2127 6505367

Patient information leaflet

Please read the entire package insert carefully, before you start to take this drug.

- Keep the package insert. You may need to read it again later.
- If you have further questions, please ask your doctor or pharmacist.
- This drug has been prescribed for your personal use and must not be given to any third person. It may be harmful to other people, even those who show the same clinical picture as you do.

This package insert contains information on:

deponit® NT 5 mg

Active substance: glyceryl trinitrate

The pharmacologically active substance is:

glyceryl trinitrate

One 9 cm^2 transdermal patch contains glyceryl trinitrate 18,7 mg. Mean rate of drug release to the skin: about 5 mg/24h

The other ingredients are:

Poly[(2-ethylhexyl)acrylate-co-vinylacetate-co-(2-hydroxyethyl)acrylate-co-(2,3-epoxypropyl)methacrylate] (67.28:5.0:15) Carrier foil: polypropylene

deponit® NT 5 mg is available in packs with 10 (N1), 30 (N2) and 100 (N3) transdermal patches.

1. What deponit® NT 5 mg is, and what it is used for?

deponit ® NT 5 mg is a drug to treat attacks of pain in the heart.

deponit® NT 5 mg is supplied by:

SCHWARZ PHARMA
Deutschland GmbH

SCHWARZ PHARMA AG
Alfred-Nobel-Straße 10
40789 Monheim, Germany
Phone: +49 2173/48-48 47
Fax: +49 2173/48-48 41
Internet: http://www.schwarzpharma.de

deponit® NT 5 mg is manufactured by:

SCHWARZ PHARMA AG
Alfred-Nobel-Straße 10
40789 Monheim, Germany
Phone: +49 2173/48-0
Fax: +49 2173/48-1608

Indications

deponit® NT 5 mg is used for the prophylaxis and long-term therapy of pain in the heart resulting from blood flow disturbances in the coronary arteries (angina pectoris).

2. Before using deponit® NT 5 mg

2.1 deponit® NT 5 mg must not be taken in case of:

- Hypersensitivity to the active substance, glyceryl trinitrate, and other nitrate compounds or to any of the other ingredients of deponit® NT 5 mg
- Acute circulatory failure (shock, circulatory collapse)
- Shock resulting from heart failure (cardiogenic shock), unless a sufficiently high filling pressure in the heart (left ventricular end-diastolic pressure) is ensured by appropriate measures
- Very low blood pressure (marked hypotension), i.e. systolic blood pressure below 90 mm Hg

During a treatment with deponit® NT 5 mg, the patient must not take drugs for the treatment of erectile dysfunction whose pharmacologically active ingredient is a phosphodiesterase type 5 inhibitor, e.g. sildenafil, vardenafil or tadalafil, because this is associated with the risk of a marked decrease in blood pressure that may have serious consequences (e.g. sudden loss of consciousness, myocardial infarction).

deponit ® NT 5 mg must not be used, either, when you have taken drugs for the treatment of erectile dysfunction whose pharmacologically active ingredient is a phosphodiesterase type 5 inhibitor, e.g. sildenafil, vardenafil or tadalafil, and you develop acute anginal complaints afterwards.

2.2 The use of deponit® NT 5 mg requires particular caution:

- If you are suffering from myocardial disease with a reduction of the ventricular cavities (hypertrophic obstructive cardiomyopathy), constrictive pericarditis or cardiac tamponade
- In case of low filling pressures, e.g. resulting from acute myocardial infarction or reduced left ventricular function (left ventricular failure). Decreasing the systolic blood pressure below 90 mm Hg should be avoided.
- If you present with stenosis of the cardiac valves of the left ventricle (aortic and/or mitral stenosis)
- If you have a tendency towards disturbances of circulatory regulation as a result of low blood pressure (orthostatic dysregulation)
- In diseases associated with elevated intracranial pressure (so far, however, further increases in pressure have been seen only after the intravenous administration of high doses of glyceryl trinitrate, a chemically related substance)

deponit® NT 5 mg is not suited to treat pain in the heart of sudden onset (e.g. acute anginal attack).

The concommittant use of heparin and deponit® NT 5 mg is associated with a decrease in the effect of heparin. The heparin dose has to be adjusted accordingly, the blood clotting parameters closely monitored. When glyceryl trinitrate is discontinued, a marked reduction of blood clotting may occur (sudden increase in PTT) so that a reduction of the heparin dose may be necessary.

Patients who have received a prior therapy with organic nitrates, e.g. isosorbide dinitrate, isosorbide-5-mononitrate, may need a higher dosage of glyceryl trinitrate to reach the desired hemodynamic effect.

In order to ensure a defibrillation or cardioversion (emergency measures during severe cardiac arrhythmias, e.g. ventricular fibrillation or ventricular flutter) the transdermal patch has to be removed.

Children

Experiences with the treatment of children have not been established so far.

Pregnancy and lactation

During pregnancy and lactation, for reasons of particular caution, you should use glyceryl trinitrate only at your doctor's explicit order, because there is not sufficient experience with using the drug in pregnant and nursing women.

Ability to drive and to operate machines

Even when used in accordance with the instructions, this drug can alter the reactivity to such an extent as to impair the ability to drive a motor-vehicle or to operate machines or to work in unsafe places. This is particularly true when the therapy is started, the dose is raised or the drug is changed, or when the drug interacts with alcohol.

2.3 Interactions with other drugs and other types of interaction

Please inform your doctor or pharmacist when you take, or have recently taken, other drugs, even if those drugs were no prescription drugs.

Enhancement of the hypotensive effect by

- Other vasodilator drugs
- Hypotensive drugs (e.g. beta-adrenergic receptor blocking agents, diuretic drugs, calcium antagonists, ACE inhibitors)
- Drugs for mental diseases such as depressions, and neuroleptics
- Alcohol
- Drugs for the treatment of erectile dysfunction whose active ingredient is a phosphodiesterase type 5 inhibitor, e.g. sildenafil, vardenafil or tadalafil (*cf.* section 2.1)

When used together with dihydroergotamine (DHE), deponit ® NT 5 mg may lead to an increase in the DHE level and thus enhance the hypertensive effect of the latter.

The concomitant use of heparin and deponit® NT 5 mg is associated with a decrease in the effect of heparin. The heparin dose has to be adjusted accordingly, the blood clotting parameters closely monitored. When glyceryl trinitrate is discontinued, a marked reduction of blood clotting may occur (sudden increase in PTT) so that a reduction of the heparin dose may be necessary.

Patients who have received a prior therapy with organic nitrates, e.g. isosorbide dinitrate, isosorbide-5-mononitrate, may need a higher dosage of glyceryl trinitrate to reach the desired hemodynamic effect.

3. How to use deponit® NT 5 mg?

Always follow your doctor's instructions precisely when taking deponit® NT 5 mg. Please ask your doctor or pharmacist, if you are not quite sure.

3.1 Mode and duration of administration

Apply the patch to a site with healthy, undamaged skin that is relatively free of creases and hairs. The site should be cleaned and dried before the application of deponit® NT 5 mg.
The best places to apply deponit® NT 5 mg are the easily reached, fairly static areas at the front or side of the chest. However, deponit® NT 5 mg may also applied to the upper arm, tigh, abdomen or shoulder. **(Figure 1)**

Figure 1

Each patch is packed in a unit dose pouch and should be left until needed. The sealed pouch is easy to tear open from one of the slits in the edge. **(Figure 2)**

Figure 2

The patch is removed from the pouch and held in both hands with the release liner (protective foil) uppermost. One half of the patch is then turned down so that the S-shaped break in the middle opens. **(Figure 3)**

Figure 3

One half of the release liner can then be peeled off. The adhesive surface should not be touched.
The patch is then applied to the site of the skin and the other half of the release liner is removed. **(Figure 4)**

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Identification No.	4010991	
Dimensions	120 x 520 mm	
Colours	black	
Operators Name	Nagler	
Creation Date	22.10.2009	
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Modification Date		
Edition No. Print	01	
FINAL APPROVAL Customer/INFB	**Date**	**Signature**
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Figure 4

The patch is then pressed down hard with the flat of the hand to ensure that the whole of the adhesive surface of the patch is adhering firmly to the skin. **(Figure 5)**

Figure 5

No skin-care products should be used before deponit® NT 5 mg is applied.

You should keep an interval of several days before using the same site of application again.

If used in accordance with the instructions, deponit® NT 5 mg adheres well to the skin and remains fully functional even when you take a bath or a shower or you are physically active. If, in rare cases, the patch comes off, apply a new one to another site.

Your doctor will determine the duration of use.

3.2 Unless otherwise prescribed by your doctor, the usual dose is:

Unless otherwise prescribed, one patch once daily is applied to the skin. The dose can be raised if necessary (e.g. two patches once daily).

As tolerance may develop, the patch should stay on the skin for only about 12 hours a day so there is a therapy-free interval of about 12 hours. Dispose of the used patch so as to prevent any misuse (e.g. by children).

Please consult your doctor if you think that the effect of deponit® NT 5 mg is too strong or too weak.

3.3 When you have taken a greater quantity of deponit® NT 5 mg than you should have done:

If overdose with major quantities of deponit® NT 5 mg is suspected, the patch must be removed immediately, and a doctor must be called at once. Depending on the extent of overdose, a marked decrease in blood pressure (hypotension) with reflex increase in pulse rate, a feeling of weakness, vertigo and dizziness, as well as headache, skin reddening, nausea, vomiting and diarrhoea may occur.

3.4 When you missed a dose of deponit® NT 5 mg:

Do not take the double dose the next time to compensate for the dose you forgot. Continue the treatment with the prescribed dose in such a case.

3.5 Consequences when the treatment with deponit® NT 5 mg is discontinued:

The therapeutic success is jeopardized.

4. What side-effects are possible?

Like all drugs, deponit® NT 5 mg may show side-effects.

The following frequency terms are used when reporting side-effects:

Very common:	Common:
More than 1 in 10 persons treated	Less than 1 in 10, but more than 1 in 100 persons treated
Uncommon:	Rare:
Less than 1 in 100, but more than 1 in 1000 persons treated	Less than 1 in 1000, but more than 1 in 10,000 persons treated
Very rare:	
Less than 1 in 10,000 persons treated, including isolated cases	

Headache ("nitrate headache") very commonly occurs, when the treatment begins; experience has shown it to subside in most cases after several days of regular use.

On the first use, but also when the dose is raised, a decrease in blood pressure and/or orthostatic hypotension (circulatory dysregulation on changes of posture) are commonly observed; these symptoms can be accompanied by an increase in pulse rate, dizziness, and feelings of vertigo and weakness.

Uncommon side-effects are:

- Nausea, vomiting, temporary skin reddening (flushing), and allergic skin reactions
- Marked decrease in blood pressure accompanied by an exacerbation of pain in the heart (anginal symptoms)
- States of collapse, often associated with cardiac arrhythmias with reduction of pulse rate (bradycardiac arrhythmias) and sudden loss of consciousness (syncopes)

Very rare side-effects are:

- Serious inflammatory skin disease (exfoliative dermatitis)

Skin reddening with or without itching and a burning sensation may occasionally occur at the site of application. Slight skin reddening will usually disappear without therapeutic measures after the patch has been removed.

An allergic reaction of the skin at the site of application (allergic contact dermatitis) has been described uncommonly.

Notes

- Due to a relative redistribution of blood flow into hypoventilated alveolar areas of the lungs, the use of deponit® NT 5 mg may result in a temporary reduction of the oxygen concentration in the arterial blood, which may induce an undersupply of the myocardium with oxygen in patients suffering from blood flow disturbances in the coronary vessels (coronary heart disease).
- A decrease in efficacy as well as a decrease in effect following the use of other nitrate-containing drugs have been described. For a decrease in, or loss of, effect to be prevented, continuously high dosages should be avoided.
- If the above-mentioned side-effects occur, please inform your doctor so that he can decide on the degree of severity and on any measures that may be necessary.
- No additional dose of deponit® NT 5 mg must be taken, once first signs of hypersensitivity appear.

Please inform your doctor or pharmacist, if you notice any side-effects not listed in this package insert.

5. What storage conditions are needed for deponit® NT 5 mg?

Store drugs out of the reach of children.

Do not use the drug after the expiry date given on the pouch and the folding box.

Do not store above 25°C.

Date of the information

March 2005

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists

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