

## PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

# Nitroderm TTS 5

## Transdermal Patch

### Active ingredient:

Each patch contains 25 mg nitroglycerin.

# Nitroderm TTS 10

## Transdermal Patch

### Active ingredient:

Each patch contains 50 mg nitroglycerin.

**Inactive ingredients:** See section 6 "Further information".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment.

Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

This medicine is not intended for children.

If an angina attack has already started, you should use fast-acting nitrate preparations (sublingual tablets or spray) instead of Nitroderm TTS patches.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is used to prevent or reduce the frequency of angina pectoris attacks.

**Therapeutic group:** A vasodilator belonging to a group of medicines called nitrates.

Nitroderm TTS is an adhesive patch containing the active substance nitroglycerin, which is delivered through the skin into the bloodstream. Nitroglycerin widens the blood vessels, which makes it easier for the heart to do its work.

### 2. BEFORE USING THE MEDICINE

#### **❗ Do not use this preparation if:**

you are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine, listed in section 6 "Further information" or to nitrates or nitrites.

you suffer from a breakdown of the blood circulation, with very low blood pressure, such as in a state of shock.

you suffer from increased intracranial pressure (a condition that your doctor will recognize and inform you about).

you suffer from a disease of the valves of the heart or an inflammatory disease of the heart.

you are currently taking a medicine to treat erectile dysfunction from the group of phosphodiesterase type 5 inhibitors (e.g., sildenafil), in light of the severe side effects that could occur (such as: fainting, myocardial infarction).

you suffer from very low blood pressure (systolic blood pressure under 90 mm/Hg).

you suffer from hypovolemia.

Do not use Nitroderm TTS for acute attacks of angina pectoris.

If one or more of these conditions apply to you, **inform the doctor without taking Nitroderm TTS.**

#### **Special warnings regarding use of the medicine**

Before treatment with Nitroderm TTS, tell the doctor if:

- You have anemia.
- You have a lung disease.
- You have a heart disease or a blood vessel disorder other than angina.

- You have recently had a heart attack, stroke or head injury.

Follow all of the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

If you have been using this medicine for several weeks or more, **do not suddenly stop using it.** Stopping suddenly may bring on attacks of angina.

Your doctor will tell you the best way to stop treatment.

#### **❗ Important information about one of the medicine's ingredients**

Before any surgery, hospital admission, emergency unit visit, or imaging procedure, inform the doctors and nurses that you are wearing a Nitroderm TTS patch which contains an aluminum layer.

#### **❗ Taking other medicines:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:**

- Medicines used to lower blood pressure
- Medicines that widen blood vessels such as other nitrates and hydralazine
- Diuretics
- Medicines used to treat depression or mood disturbances
- Medicines used to treat mental disorders (tranquilizers)
- Medicines used to treat migraine (dihydroergotamine)
- Medicines used to treat erectile dysfunction (inhibitors of an enzyme called phosphodiesterase type 5, including sildenafil)
- Aspirin and medicines from the non-steroidal anti-inflammatory group

#### **❗ Taking the medicine with food, alcohol consumption**

Be careful when drinking alcohol as your blood pressure may fall more than usual and cause a feeling of dizziness or fainting.

#### **❗ Elderly patients (65 years of age or older)**

There is no specific information regarding use of Nitroderm TTS in elderly patients (65 years of age or older). Your doctor will advise you about this.

#### **❗ Children and adolescents**

This medicine is not intended for children.

#### **❗ Pregnancy and breast-feeding**

You should tell your doctor if you are pregnant, or if you plan to become pregnant. Your doctor will discuss with you the potential risks of taking Nitroderm TTS during pregnancy.

It is not known whether nitroglycerin passes into the breast milk. You should tell your doctor if you are breast-feeding.

#### **❗ Driving and using machines**

Use of this medicine may cause dizziness or fainting, especially at the start of treatment. You should, therefore, be careful when driving a car, operating dangerous machinery or doing other activities that require you to be alert.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

#### **Dosage:**

The dosage and treatment regimen will be determined by the doctor only.

#### **Do not exceed the recommended dose.**

Your doctor will determine which type of patch you should use (Nitroderm TTS 5 or 10) and how many patches you should apply, depending on your individual needs. Your doctor will also tell you when and how often to change your patch.

#### **Directions for use:**

You should normally put on a new patch once a day, usually in the morning.

Your doctor may tell you to remove the patch for 8-12 hours out of every 24 hours, usually at night (called **patch-off period**). If you feel your medicine is not helping you, please tell your doctor.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dosage of the medicine.

Use this medicine at set intervals as determined by the attending doctor.

#### **Where to apply the patch?**

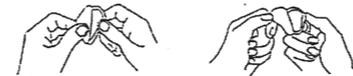
Choose any area of skin on the upper half of your body (from the waist until the shoulders) or the upper arm. The skin should be healthy (not inflamed, broken, or irritated). To help the patch stick, the skin should be clean, non-hairy, dry, and free of creams, lotions, oil, or powder. You should apply the patch to a different area of skin each day. Wait several days before using the same area again.

#### **Opening the sachets:**

Each Nitroderm TTS patch is packed in a separate sachet. The sticky surface is covered with a white plastic protective backing.



Tear open the sachet where marked. Remove the patch from the sachet. Carefully hold the patch with the opening tab facing upwards and the white protective backing facing you.



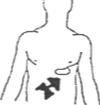
#### **Removing the protective backing:**

Firmly bend the tab with your thumb. Peel off the white protective backing from the patch starting at the tab. Do not touch the sticky surface of the patch.

#### **Applying the patch:**

Press the sticky side of the patch firmly to the area of skin you have chosen (upper half of your body or upper arm) with the palm of your hand for 10-20 seconds.

Make sure that the patch sticks well, especially around the edges. Do not test the patch by pulling it once it is on your skin.



#### **When and how to remove the patch:**

Leave the patch in place on your skin for as long as the doctor tells you to. Peel it off and fold it in half, pressing the sticky sides together.

Do not cut or tear the patch.

Throw the used patch away, ensuring that it is out of the reach of children.

Any adhesive left on the skin can be removed with alcohol.

Stick a new patch on a different area of your skin.

#### **If the patch becomes wet:**

Bathing or showering, swimming or exercising will not usually affect the patch if it has been correctly applied.

#### **If the patch falls off:**

It is unlikely that the patch will fall off, but if it does, discard it and put on a new patch as soon as possible. You should put on your next patch at your regular time.

#### **If you forget to apply Nitroderm TTS patch**

If you forget to change a patch at the correct time, do not worry. Change it as soon as you remember, respecting any prescribed patch-off period, if you have been instructed to do so by the doctor. However, if the time to change the next patch is approaching, skip the forgotten patch and apply the next patch at the correct time.

#### **If you use more Nitroderm TTS patches than you should**

If you have accidentally used more patches than your doctor prescribed, contact a doctor immediately. You may require medical attention.

#### **If you stop using Nitroderm TTS patches**

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you have been using Nitroderm TTS for several weeks or more, do not suddenly stop using it. Stopping suddenly may bring on attacks of angina. Adhere strictly to the doctor's instructions.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

### 4. SIDE EFFECTS

As with any medicine, use of Nitroderm TTS may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

These effects usually disappear within a short time following the period of adaptation to the preparation. If they continue for more than a few days or worsen, refer to the attending doctor.

#### **Side effects that require special attention:**

In the event that one of the effects listed below occurs, remove the patch and contact the doctor immediately:

Headache, dizziness, tiredness, difficulty breathing, bluish skin discoloration, weak and very fast heart beats, unusual weakness.

Signs of allergy such as skin rash and/or prickling, swelling of the face, lips, tongue and/or other parts of the body, fainting.

Very common side effects - effects that occur in more than 1 user in 10:

- Nausea
- Vomiting

Common side effects - effects that occur in 1-10 in 100 users:

- Headache, which may need treatment with an analgesic.

Uncommon side effects - effects that occur in 1-10 in 1,000 users:

- Skin irritation: the skin under the patch may become red and itchy. This will disappear within a day of removing the patch.
- Skin allergies: the skin under the patch may become very red and swollen, or form blisters. If you develop a generalized rash covering extensive areas of skin in your body, report this to your doctor.

Rare side effects - effects that occur in 1-10 in 10,000 users:

- Reddening of the face or feeling dizzy when you get up quickly from a lying or sitting position, due to low blood pressure. Getting up slowly may help. If you feel dizzy, sit or lie down.
- Fast heartbeat.

Very rare side effects - effects that occur in less than 1 user in 10,000:

- Dizziness.

Other side effects (unknown frequency):

- Heart-related effects: feeling of especially strong, fast or irregular heart beats (palpitations). Contact your doctor if this affects you severely.
- Skin-related effects: rash.

If the side effects affect you severely, inform the doctor.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health using the online form at the following link:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il>

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- Storage conditions: Store below 25°C.

- Use the patch immediately after removing it from the sachet.

### 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Silica aerogel, silicone oil, ethylene-vinylacetate copolymer, medical adhesive CH 15.

What does the medicine look like and what are the contents of the package:

Nitroderm TTS 5: Flat patch with "CG DOD" printed on the orange-grey side; the other side is off-white colored.

Nitroderm TTS 10: Flat patch with "CG DPD" printed on the orange-grey side; the other side is off-white colored.

Package sizes:

10 sachets in each package

**License Holder and address:**  
Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

**Manufacturer and address:**  
Novartis Pharma Stein AG, Stein, Switzerland  
for Novartis Pharma AG, Basel, Switzerland.

This leaflet was checked and approved by the Ministry of Health in July 2015.

**Registration number of the medicine** in the National Drug Registry of the Ministry of Health:

Nitroderm TTS 5 - 118 55 22967

Nitroderm TTS 10 - 118 56 21607