**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**
**PATIENT MEDICATION INFORMATION**

# TRANSDERM-NITRO®
## nitroglycerin patch

Read this carefully before you start taking **TRANSDERM-NITRO®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRANSDERM-NITRO®**

**Serious Warnings and Precautions**

Do **NOT** take any medication for the treatment of impotence (erectile dysfunction) such as VIAGRA* (sildenafil citrate), CIALIS* (tadalafil), LEVITRA* or STAXYN* (vardenafil) while using **TRANSDERM-NITRO®**. Using **TRANSDERM-NITRO®** together with medication for erectile dysfunction can result in life-threatening low blood pressure (hypotension) causing fainting, heart attack and death.

### What is TRANSDERM-NITRO® used for?
**TRANSDERM-NITRO®** is used in adults to prevent angina (chest pain). It can be used alone or together with other antianginal agents such as beta-blockers and/or calcium channel blockers.

**TRANSDERM-NITRO®** is not intended to be used for acute angina attacks. Sublingual nitroglycerin medications should be used if you are having an acute angina attack.

### How does TRANSDERM-NITRO® work?
When TRANSDERM-NITRO® is applied to the skin, it releases small amounts of nitroglycerin at a steady rate. This passes through the skin, into your bloodstream. It relaxes and widens the blood vessels and increases the supply of blood and oxygen to the heart. This helps prevent attacks of anginal pain (chest pain) from occurring.

### What are the ingredients in TRANSDERM-NITRO®?
Medicinal ingredients: Nitroglycerin
Non-medicinal ingredients: colloidal silicon dioxide, lactose, and silicone medical fluid
Patch layers contain aluminized plastic, ethylene/vinyl acetate copolymer and hypoallergenic silicone adhesive.

### TRANSDERM-NITRO® comes in the following dosage forms:
TRANSDERM-NITRO® is available in three different patch strengths:
TRANSDERM-NITRO® 0.2 mg/hour (10 $cm^2$)
TRANSDERM-NITRO® 0.4 mg/hour (20 $cm^2$)
TRANSDERM-NITRO® 0.6 mg/hour (30 $cm^2$)

**Do not use TRANSDERM-NITRO® if you:**

- are allergic to nitroglycerin, nitrates, nitrites or any non-medicinal ingredient in the formulation.
- have had a recent heart attack, or other serious heart problems, stroke or head injury
- experience lightheadedness, dizziness or fainting when going from lying or sitting to standing up (postural hypotension).
- have narrowing of the heart valves.
- have a condition caused by an increase in normal brain pressure (increased intracranial pressure).
- have an eye disease called closed angle glaucoma or any other condition that increases the pressure in your eyes.
- have severe anemia (low iron levels in your blood or low red blood cell count).
- are taking medication for erectile dysfunction such as VIAGRA* (sildenafil citrate), CIALIS* (tadalafil), LEVITRA* or STAXYN* (vardenafil).
- are taking medications used to treat high blood pressure in your lungs such as ADEMPAS* (riociguat), REVATIO* (sildenafil citrate) or ADCIRCA* (tadalafil).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRANSDERM-NITRO®. Talk about any health conditions or problems you may have, including if you:**

- have heart failure
- have low blood pressure or take diuretics ("water pills")
- have lung disease
- are breast feeding, pregnant or intend to become pregnant. Your healthcare professional will decide whether you should use TRANSDERM-NITRO® and what extra care should be taken during its use.
- are less than 18 years old or older than 65 years of age
- are dehydrated or suffer from excessive vomiting, diarrhea or sweating
- have angina due to hypertrophic cardiomyopathy

**Other warnings you should know about:**

**Driving and using machines:** Before you perform tasks which may require special attention, wait until you know how you respond to TRANSDERM-NITRO®. Dizziness, lightheadedness, or fainting can occur, especially after the first dose and when the dose is increased.

Tolerance to TRANSDERM-NITRO® and similar drugs can occur after long periods of use. Chronic use can lead to angina attacks being brought on more easily. Do not suddenly stop using TRANSDERM-NITRO®. Talk to your healthcare professional if you wish to discontinue using TRANSDERM-NITRO®.

TRANSDERM-NITRO® is not for use in children.

After normal use, there is enough residual nitroglycerin in discarded TRANSDERM-NITRO® patches that they are a potential hazard to children and pets.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**Serious Drug Interactions**

**If you are currently taking medications for the treatment of impotence (erectile dysfunction), such as sildenafil citrate, tadalafil or vardenafil or any other similar medication (PDE5 inhibitors), the use of TRANSDERM-NITRO® may lead to extreme low blood pressure resulting in fainting, heart attack and death.**

If you are being treated with any of these drugs and need TRANSDERM-NITRO® (e.g. in case of chest pain caused by an acute attack of angina) please seek emergency medical assistance immediately.

**The following may interact with TRANSDERM-NITRO®:**

- Do not take any drugs used to treat erectile dysfunction such as VIAGRA* (sildenafil citrate), CIALIS* (tadalafil), LEVITRA* or STAXYN* (vardenafil) if you are using TRANSDERM-NITRO®.
- Drugs used to treat high blood pressure. such as:
    - Diuretics ("water pills")
    - Calcium Channel Blockers (e.g. diltiazem, nifedipine, verapamil)
    - ACE Inhibitors
    - Beta-Blockers
- Drugs used to treat depression called "tricyclic antidepressants".
- Tranquillizers.
- Other drugs that may have the same effect as TRANSDERM-NITRO®.
- Alcohol
- Drugs used to treat migraine headaches (e.g. dihydroergotamine)
- Acetylsalicylic acid (Aspirin*)
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling (such as ibuprofen, naproxen, and celecoxib).
- Do not use TRANSDERM-NITRO®.if you are taking drugs used to treat high blood pressure in your lungs such as ADEMPAS* (riociguat), REVATIO* (sildenafil citrate) or ADCIRCA* (tadalafil).

**How to use TRANSDERM-NITRO®:**

**1. Deciding Where to Apply the Patch**

Choose any area of skin which is most comfortable for you, but <u>not</u> past the knees or elbows. Many patients prefer the chest. It is best if the area is hairless. Avoid skin folds. The skin should not be scarred, burned, irritated or broken, since this may alter the amount of medicine you get. You should apply the patch to a different area of skin each day, and wait several days before using the same area again. To help you remember to change the site of patch application regularly, you may wish to use the same area of skin on a particular day of the week.

For example:

| | | |
|---|---|---|
| Sunday | 1 | |
| Monday | 2 | |
| Tuesday | 3 | |
| Wednesday | 4 | |
| Thursday | 5 | |
| Friday | 6 | |
| Saturday | 7 | |
| Sunday | 1 | |
| Monday | 2 | etc. |

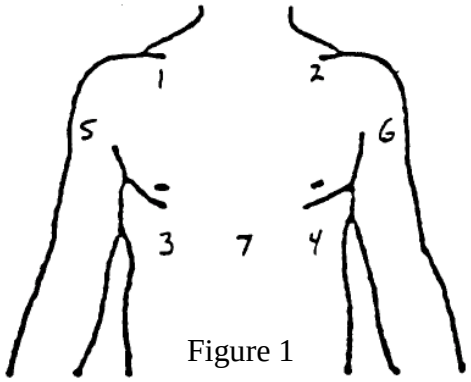

Figure 1

## 2. Preparing the Skin

In order for the patch to stick, the skin must be clean and dry without any creams, lotions, oil or powder. If hair is likely to interfere with the patch sticking or removal, it can be clipped but not shaved since this may irritate the skin.

## 3. Opening the Pouch

Each TRANSDERM-NITRO® patch is individually sealed in a protective pouch. Tear open this pouch at the indentation and remove the patch. Do not use scissors, since you may accidentally cut the patch. (Figure 2 & 3). TRANSDERM-NITRO® is designed as a complete unit. Do not cut the patch.

Figure 2

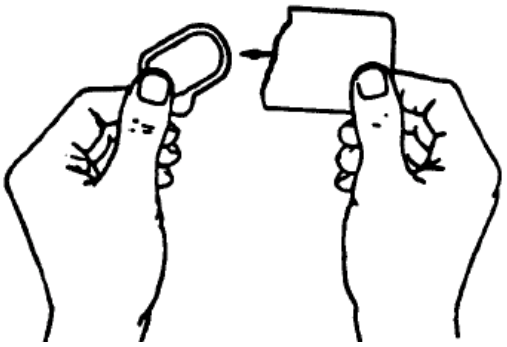

Figure 3

**4. Recognizing the Patch and Removing the Liner**

The patch itself is tan-coloured. A plastic liner covers the adhesive (sticky) side of the patch during storage, and must be removed and discarded before patch use. The plastic liner will be either white on both sides or clear, depending on the size of the patch.

Pick up the patch lengthwise with the tab up, and the plastic liner facing you (Figure 4). If you are left-handed it might be easier to start with the tab down and the tan-coloured side facing you. Firmly bend the tab forward with the thumb. With both thumbs, carefully remove the plastic protective liner from the patch starting at the tab (Figure 5). Continue to peel back the plastic liner along the length of the patch, allowing the patch to rest on the outside of your fingers. (Figure 6)

Figure 4

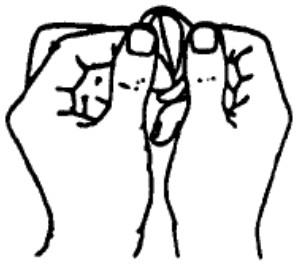

Figure 5

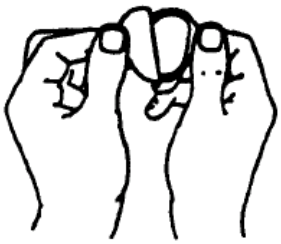

Figure 6

By removing the plastic liner you have exposed the adhesive side. The adhesive side of the patch appears to have a silver-coloured edge. From this side you should also be able to see the white cream containing nitroglycerin within the patch.

Avoid touching the adhesive. If another person applies the patch for you, he/she must be careful not to touch the surface which will be applied to the skin. Apply the tan-coloured patch immediately after opening the pouch and removing the plastic liner. Discard the plastic liner.

## 5. Applying the Patch

Remember, the skin should be clean and dry without creams, lotions, oil or powder. Place the exposed adhesive side of the patch (i.e. the silver-edged side) on the area you have chosen as explained above. Press it firmly in place with the palm of your hand for 10 - 20 seconds (Figure 7). Circle the outside edge of the patch with one or two fingers. Once the patch is in place, do not test the adhesion by pulling on it. When applied correctly, the tan-coloured side will be seen when looking at the patch on the skin.

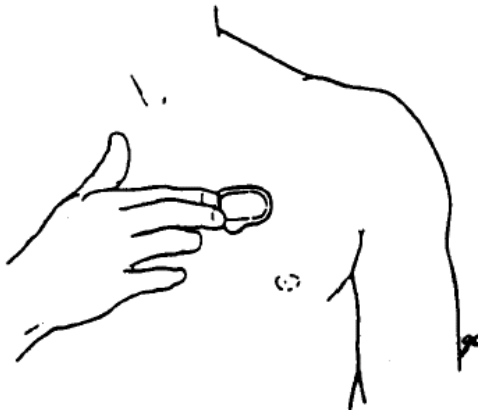

Figure 7

## 6. When and How to Remove the Patch

The TRANSDERM-NITRO® patch should be changed according to the schedule prescribed by your doctor. It is important to respect the patch-off period recommended by your doctor. If you forget to remove it at the scheduled time just remove it as soon as possible and continue to follow your original schedule.

Remove the patch by pulling on the tab. Each patch can only be applied once. After use, fold the patch in half with the adhesive side inwards. Throw it away safely out of the reach of children. Any adhesive left on the skin can be removed with rubbing alcohol or light mineral oil.

## 7. What to Do if TRANSDERM-NITRO® Falls Off

Contact with water (as in bathing, swimming, showering) or physical activity will not affect the patch. It is unlikely that the patch will fall off. If the patch does fall off, discard it and put a new patch on a different area of skin. Continue to follow your original schedule.

**Usual adult dose:**
The daily dosage schedule is based on intermittent therapy (patch on period followed by a patch-off period) to prevent the development of tolerance to nitroglycerin.

Starting dose is one TRANSDERM-NITRO® 0.2 mg/hour patch (10 cm²), usually applied in the morning. If 0.2 mg/hour (10 cm²) is well tolerated, the dose can be increased to 0.4 mg/hour (20 cm²) if required. A maximum of 0.8 mg/hour (40 cm²) may be used.

**Overdose:**

If you think you have used too much TRANSDERM-NITRO®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

## What are possible side effects from using TRANSDERM-NITRO®?

These are not all the possible side effects you may feel when taking TRANSDERM-NITRO®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Headache
- Flushing of the face
- Nausea
- Vomiting
- Rash, redness, itching and/or burning in the area where the patch is applied.

| Serious side effects and what to do about them | | | |
|---|---|---|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| **UNKNOWN** | | | |
| **Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing. | | | √ |
| **Unstable Angina:** chest pain that has changed or gotten worse, nausea, anxiety, sweating, shortness of breath, dizziness, fatigue | | | √ |
| **Increased levels of methemoglobin in the blood**: shortness of breath, blue or purple coloration of the lips, fingers and/or toes, headache, fatigue, dizziness, loss of consciousness. | | | √ |
| **Low Blood Pressure:** dizziness, fainting, lightheadedness, fast heartbeat. May occur when you go from lying or sitting to standing up. | √ | | |
| **High Blood Pressure:** headache, vision problems, irregular heartbeat | √ | | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
**3 ways to report**:

- Online at MedEffect (www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (www.healthcanada.gc.ca/medeffect).

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**
TRANSDERM-NITRO® should be stored at temperatures below 25˚C. Do not freeze. Do not store it out of the individually sealed pouch.

TRANSDERM-NITRO® should be kept out of the reach of children and pets both before use and when disposing of used patches. If your patch becomes stuck to a child or another person, remove the patch at once and contact a doctor.

**If you want more information about TRANSDERM-NITRO®:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://www.hc-sc.gc.ca); the manufacturer's website http://www.novartis.ca or by calling 1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc., 385 Bouchard, Dorval, Quebec, H9S 1A9.

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