

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Mylan-Nitro Patch 0.2

Nitroglycerin Transdermal System, Mfr. Std.

0.2 mg/hour

Mylan-Nitro Patch 0.4

Nitroglycerin Transdermal System, Mfr. Std.

0.4 mg/hour

Mylan-Nitro Patch 0.6

Nitroglycerin Transdermal System, Mfr. Std.

0.6 mg/hour

Mylan-Nitro Patch 0.8

Nitroglycerin Transdermal System, Mfr. Std.

0.8 mg/hour

Read this carefully before you start taking Mylan-Nitro Patch and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your prescribing physician about your medical condition and treatment and ask if there is any new information about Mylan-Nitro Patch.

What is Mylan-Nitro Patch used for?

Mylan-Nitro Patch is used in adults to prevent angina (chest pain).

Mylan-Nitro Patch 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 Mylan-Nitro Patch work?

Mylan-Nitro Patch is a patch applied directly to the skin. The nitroglycerin passes from the adhesive surface through the skin – allowing medication to be absorbed directly into the bloodstream. Nitroglycerin causes the blood vessels to relax and increases the supply of blood and oxygen to the heart reducing the likeliness of having an angina attack.

The amount of Mylan-Nitro Patch you need will depend upon your body's needs. Observe the dosing instructions given to you by your prescribing physician and report to him/her if your condition changes.

What are the ingredients in Mylan-Nitro Patch?

Medicinal ingredients: Nitroglycerin

Non-medicinal ingredients: Acrylic adhesive, polyolefin film, white ink and silicone coated polyester film.

Mylan-Nitro Patch comes in the following dosage forms:

Transdermal patch: 20.7 mg (0.2 mg/hour), 41.4 (0.4 mg/hour), 62.2 (0.6 mg/hour) and 82.9 mg (0.8 mg/hour).

Do not use Mylan-Nitro Patch if you:

- are allergic to nitroglycerin, nitrates, or to any non-medicinal ingredient in the formulation.
- 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).
- 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 severe anemia (low iron levels in your blood or low red blood cell count).
- have narrowing of the heart valves.
- have an eye disease called closed angle glaucoma or any other condition that increases the pressure in your eyes.

To help avoid side effects and ensure proper use, talk to your prescribing physician before you take Mylan-Nitro Patch 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 Mylan-Nitro Patch and what extra care should be taken during its use.
- are less than 18 years old

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 Mylan-Nitro Patch. Dizziness, lightheadedness, or fainting can occur, especially after the first dose and when the dose is increased.

Tolerance to Mylan-Nitro Patch 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 Mylan-Nitro Patch. Talk to your prescribing physician if you wish to discontinue using Mylan-Nitro Patch.

Tell your prescribing physician about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Mylan-Nitro Patch:

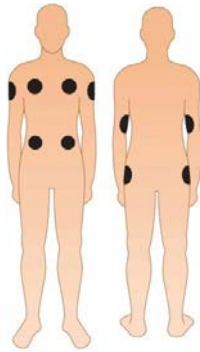
- Do not take any drugs used to treat erectile dysfunction such as VIAGRA* (sildenafil citrate), CIALIS* (tadalafil), LEVITRA* or STAXYN* (vardenafil) if you are using Mylan-Nitro Patch.
- Do not use Mylan-Nitro Patch if you are taking drugs used to treat high blood pressure in your lungs such as ADEMPAS* (riociguat), REVATIO* (sildenafil citrate) or ADCIRCA* (tadalafil).
- Drugs used to treat high blood pressure.
- Diuretics (“water pills”)
- Drugs used to treat depression called “tricyclic antidepressants”.
- Tranquillizers.
- Other drugs that may have the same effect as Mylan-Nitro Patch.
- Alcohol.
- Drugs used to treat migraine headaches (such as dihydroergotamine).
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling (such as ibuprofen, naproxen, and celecoxib).
- Acetylsalicylic acid (Aspirin)

How to use Mylan-Nitro Patch:

1. Patches should be applied for 12 to 14 hrs, and taken off for 10 to 12 hrs.
2. Do not cut Mylan-Nitro Patch, use part patches or apply more than one patch at a time.
3. Do not reuse patch. Discard after first use in a safe manner.
4. Allow Mylan-Nitro Patch to stay in place as directed by your prescribing physician.
5. Showering is permitted with Mylan-Nitro Patch in place.
6. Mylan-Nitro Patch is packaged so that you have a 30-day supply. Be sure to check your supply periodically. Before it runs low, you should visit your pharmacist for a refill or ask your prescribing physician to renew your Mylan-Nitro Patch prescription.
7. It is important that you do not miss a day of your Mylan-Nitro Patch therapy. If your schedule needs to be changed, your prescribing physician will give you specific instructions.
8. Mylan-Nitro Patch has been prescribed for you. Do not give your medication to anyone else.
9. Notify your prescribing physician if your condition changes.

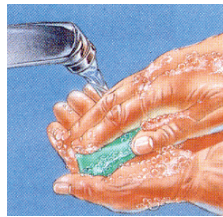
Placement area

- Apply to clean, dry, hairless areas of the skin, each successive application to a different site. Select a reasonably hair-free application site. An appropriate application area can be shaved if required.
- Avoid extremities below the knee or elbow, skin folds, scar tissue, burned or irritated areas.

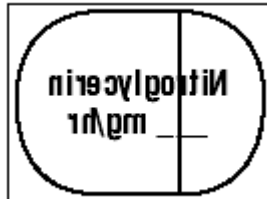


Application

1. Wash hands before applying



2. Open the pouch at the tear mark. Carefully remove the patch.
3. The patch is attached to a clear liner. The liner has a slit which divides it into two strips.
4. Hold the patch so the slit is facing toward you and the slit in an up and down position



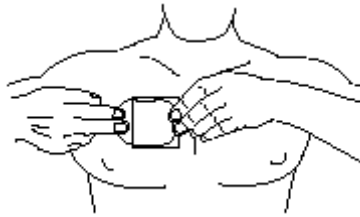
5. Bend both sides of the liner away from you at the slit.



6. Slowly peel off only one of the strips of the clear liner. Do not touch the exposed sticky side of the patch.



7. Using the remaining strip as a “handle”, apply the exposed sticky side of the patch to the skin. Press the sticky side on the chosen skin site and smooth down.



8. Fold back the unattached side of the patch. Grasp the remaining strip and remove it while applying the remainder of the patch to the skin. Press the patch on the skin and smooth down with the palm of your hand for about 30 seconds. Once the patch is in place, do not test the adhesion by pulling on it.



When Mylan-Nitro Patch is applied to your body, the nitroglycerin contained in the patch begins to flow from the adhesive surface through your skin at a uniform rate.

9. After applying the patch, wash hands to remove any drug.



Removal

1. Grasp the edge of the patch gently, and slowly peel the patch away from the skin.
2. Wash skin area with soap and water. Towel dry. Wash hands.
3. After removal, the patch should be discarded in a manner that prevents accidental application or ingestion by children or pets.
4. You should use a different application site every day.

Please note:

Contact with water, as in bathing, swimming, or showering will not affect the patch. In the unlikely event that a patch falls off, discard it and put a new one on a different skin site.

Important:

Your doctor may decide to increase or decrease the size of the patch, or prescribe a combination of patches, to suit your particular needs. The dose may vary depending on your individual response to the patch.

This patch is to be used for preventing angina, not for treating an acute attack.

Skin care

1. After you remove Mylan-Nitro Patch, your skin may feel warm and appear red. This is normal. The redness will disappear in a short time. If the area feels dry, you may apply a soothing lotion after washing.
2. Any redness or rash that does not disappear within a few hours should be called to your prescribing physician's attention.

Usual adult dose:

The starting dose is one Mylan-Nitro Patch 0.2 mg/hr patch (7.4 cm²), usually applied in the morning. If well tolerated and depending on response, dose may be increased to 0.4 mg/hr, maximum 0.8 mg/hr.

Patches should be applied for 12 to 14 hrs, and taken off for 10 to 12 hrs. Apply to clean, dry, hairless areas of the skin, each successive application to a different site.

Overdose:

The patch should be removed immediately and the underlying skin washed thoroughly.

<p>If you think you have taken too much Mylan-Nitro Patch, contact your prescribing physician, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.</p>

Missed Dose:

If you have forgotten to apply Mylan-Nitro patch at the scheduled time apply it as soon as you remember.

What are possible side effects from using Mylan-Nitro Patch?

These are not all the possible side effects you may feel when taking Mylan-Nitro Patch. If you experience any side effects not listed here, contact your prescribing physician. Please also see Warnings and Precautions.

Side effects may include:

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

Mylan-Nitro Patch may also lower the blood pressure and cause dizziness, lightheadedness, or a fainting feeling, especially when you get up quickly from lying or sitting. Getting up slowly may help. If you feel dizzy, sit or lie down. You may be more likely to experience headaches, dizziness, or lightheadedness if you drink alcohol, stand for a long time, or if the weather is hot. While using Mylan-Nitro Patch, be careful about the amount of alcohol you drink. Also use extra care when exercising, standing for a long time, driving, or during hot weather.

Serious side effects and what to do about them			
Symptom / effect	Talk to your prescribing physician		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.			√
COMMON Low Blood Pressure: dizziness, fainting, lightheadedness may occur when you go from lying or sitting to standing up.	√		
UNKNOWN Increased levels of methemoglobin in the blood: shortness of breath, blue or purple colouration of the lips, fingers and/or toes, headache, fatigue, dizziness, loss of consciousness.			√

UNKNOWN Chest pain (angina)	√		
UNKNOWN Irregular, fast or slow heartbeat		√	
UNKNOWN Heart Attack: crushing chest pain that radiates into the arm or jaw, shortness of breath, nausea, vomiting.			√

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 prescribing physician.

Reporting Side Effects

You can report any suspected side effects associate with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Store between 15°C to 30° C. Do not refrigerate.
Keep out of reach and sight of children.

If you want more information about Mylan Nitro-Patch:

- 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by calling 1-844-596-9526

This document can be found at: www.mylan.ca.

The full Product Monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC at: 1-844-596-9526

This leaflet was prepared by Mylan Pharmaceuticals ULC
Etobicoke, Ontario M8Z 2S6

Revised on: June 19, 2019



Mylan Pharmaceuticals ULC
Etobicoke, ON M8Z 2S6
1-844-596-9526
www.mylan.ca