

PACKAGE LEAFLET

Package leaflet: Information for the user

Cardioplast 0.2 mg/h transdermal patches
Cardioplast 0.4 mg/h transdermal patches
Cardioplast 0.6 mg/h transdermal patches

Glyceryl trinitrate

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 Cardioplast is and what it is used for
2. What you need to know before you use Cardioplast
3. How to use Cardioplast
4. Possible side effects
5. How to store Cardioplast
6. Contents of the pack and other information

The full name of your product is Cardioplast 0.2 mg/h transdermal patch, Cardioplast 0.4 mg/h transdermal patch or Cardioplast 0.6 mg/h transdermal patch, however, throughout the leaflet it will be referred to as Cardioplast.

1. What Cardioplast is and what it is used for

Cardioplast is an adhesive patch that delivers a medicine called glyceryl trinitrate. Glyceryl trinitrate is contained in the adhesive and when the patch is in contact with the skin the glyceryl trinitrate passes slowly and steadily from the patch through the skin and into the bloodstream.

Glyceryl trinitrate belongs to a group of medicines called nitrate vasodilators which are used to treat the symptoms of angina (chest pain). Vasodilators work by widening of the blood vessels and therefore an increase in blood flow, letting more blood and oxygen reach the heart.

Angina usually occurs as a pain or tightness in the chest although it may be felt in the neck or arm. The pain occurs when the heart muscle does not receive the oxygen it needs to do the work it has to do.

Cardioplast is used to prevent symptoms of angina; it is not for treatment of an acute attack.

You should use your usual tablets or spray under the tongue for treatment of acute attacks.

2. What you need to know before you use Cardioplast

Do not use Cardioplast:

- if you are allergic to glyceryl trinitrate or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any other medicines containing nitrates
- if you have low levels of haemoglobin – a substance contained within the red blood cells which is responsible for carrying oxygen around the body (anaemia)
- if you have heart problems other than angina like disorders of the heart valves, inflammation of the heart lining (constrictive pericarditis), thickening of the heart muscle (hypertrophic

obstructive cardiomyopathy), build-up of fluid or blood in the space between the heart muscle and covering sac of the heart (cardiac tamponade)

- if you have low blood pressure or blood volume
- if you have 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 eye condition which causes a sudden increase in pressure in the eye causing visual disturbances) (closed-angle glaucoma)
- if you have failure of the circulation with very low blood pressure (shock)
- if you are taking medicines for failure to achieve an erection such as sildenafil, tadalafil or vardenafil. If you use these medicines together with Cardioplast, a severe and possibly dangerous fall in blood pressure can occur. This could result in collapse, unconsciousness and could be fatal.

Warning and precautions

Talk to your doctor or pharmacist before using Cardioplast if you have any of the following conditions:

- an underactive thyroid gland
- severe lack of food (malnourishment)
- liver or kidney disease
- very low body temperature (hypothermia)
- have had recent heart attack or heart failure
- have lung disease
- have previously suffered from closed-angle glaucoma.

If you are having certain procedures which use magnetic or electrical fields like a magnetic resonance imaging scan (MRI scan), cardioversion or defibrillation (an electric shock used to return the heart to its normal rhythm) or diathermy (where body tissues are heated electrically to treat or help certain conditions), you will need to remove your patch.

Children and adolescents

Cardioplast should not be used by children and adolescents because the safety and efficacy has not been established.

Other medicines and Cardioplast

Do not take Cardioplast with medicines used for failure to achieve an erection such as sildenafil, tadalafil or vardenafil. If you use these medicines together with Cardioplast, a severe and possibly dangerous fall in blood pressure can occur. This could result in collapse, unconsciousness and could be fatal.

Talk to your doctor or pharmacist if you are taking any of the following medicines. Taking these at the same time as Cardioplast may lower your blood pressure too much:

- medicines to lower your blood pressure such as beta-blockers (e.g. propranolol), ACE inhibitors (e.g. enalapril, perindopril), calcium channel blockers (e.g. felodipine, diltiazem)
- water tablets (diuretics)
- medicines for anxiety or depression such as tricyclic antidepressants or tranquillisers
- aspirin
- amifostine (a medicine used to reduce the side effects of certain cancer treatments or radiotherapy)

Dihydroergotamine, a medicine used to treat migraine, neutralizes the effect of Cardioplast. This causes the blood vessels in the heart to contract.

The effect of Cardioplast may be reduced if you take anti-inflammatory pain killers (e.g. diclofenac) at the same time as you use your patch.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Cardioplast with alcohol

Do not drink alcohol whilst using Cardioplast as it may cause your blood pressure to fall. This may make you feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is no information on the excretion of this medicine into breast milk.

Driving and using machines

Cardioplast may impair your reactions, or make you feel dizzy, light-headed upon standing or faint, especially at the start of treatment or when the dose is adjusted. Do not drive or use machines if you are affected in this way.

3. How to use Cardioplast

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

Your doctor may tell you to remove the patch after a period shorter than 24 hours to prevent tolerance developing to the medicine (reduced effect due to your body getting used to the medicine).

He may also tell you to apply the patch in the morning or at night. You should usually apply a new patch at the same time each day on a different area of clean and dry skin to prevent local irritation.

The recommended dose is one Cardioplast 0.2 mg/h equivalent to 5 mg/24 h patch applied to the skin once daily for a period of approximately 12 -16 hours with patch-free interval of 8-12 hours.

If necessary, the dosage may be increased to one Cardioplast 0.4 mg/h equivalent to 10 mg/24 h patch once daily or to a maximum of one Cardioplast 0.6 mg/h equivalent to 15 mg/24 h patch in each 24 hour period.

How to apply your patch

- The patch should be placed on a reasonably hair-free area on the outer upper arm or chest. If there is hair, do not shave it (shaving irritates the skin). Instead, clip the hair as close to the skin as possible. Avoid areas below the waist or elbow, skin folds, scars or burnt or irritated area.
- Do not use any greasy substances (creams, ointments) on the skin before applying the patch.
- Do not apply the patch immediately after showering or bathing. It is best to wait until you are certain the skin is completely dry.
- **Do not tear or cut your patch.**

Putting a patch on

1.

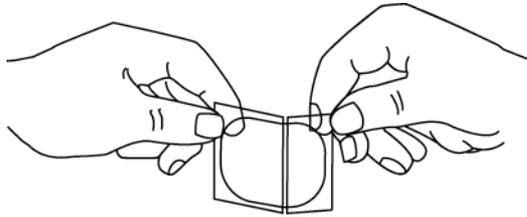
Each Cardioplast patch is individually sealed in a protective package.

- Wash your hands before putting the patch on.
- Open the sachet at the tear mark.
- Carefully remove the patch.
- The patch is printed accordingly with the wording:
“Glyceryl trinitrate 0.2 mg/h (5mg/24 h)” for Cardioplast 0.2 mg/h transdermal patch
“Glyceryl trinitrate 0.4 mg/h (10mg/24 h)” for Cardioplast 0.4 mg/h transdermal patch
“Glyceryl trinitrate 0.6 mg/h (15mg/24 h)” for Cardioplast 0.6 mg/h transdermal patch
- The liner has a slit which divides it into two strips.

- Hold the patch with the wording facing away from you.
- The slit should now be facing toward you.
- Rotate the patch as necessary to place the slit in an up and down position.

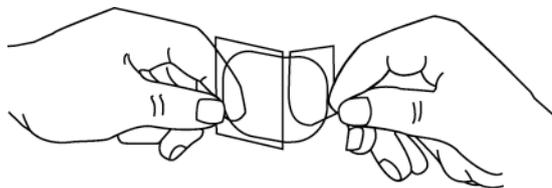
2.

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



3.

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



4.

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



5.

- 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.
- Once the patch is in place, do not test how well it is stuck on by pulling on it.
- When Cardioplast is applied to your body, the active ingredient contained in the patch begins to flow from the sticky surface through your skin at a regular rate.

6.

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

Please Note: Once the patch is in place, swimming, showering or bathing should not affect it. However, if the patch does fall off, dispose of it carefully and put a new patch on a different skin site.

How to remove your patch

1. Press down the centre of the patch to raise its outer edge away from the skin.
2. Grasp the edge gently and slowly peel off the patch.
3. Wash the skin where the patch was applied with soap and water and towel dry. Wash your hands.

How to dispose of the patch

- As soon as you take the patch off, fold it firmly in half so that the sticky side sticks to itself.
- If possible, put it back in its original pouch and put the pouch in the bin with your household rubbish.

Even used patches contain some medicine which may harm children, so keep your used patches out of the reach and sight of children.

If you use more Cardioplast than you should

If you or someone else applies too many patches at once, remove the patches carefully and wash the skin thoroughly to prevent any more medicines being absorbed. Too much glyceryl trinitrate can cause your blood pressure to drop with a fast heart rate, make you feel light-headed or cause you to faint.

If you forget to use Cardioplast

If you forget to change your patch, do so as soon as you remember. Then go on as before. Do not apply two patches to make up for the forgotten dose.

If you stop using Cardioplast

Do not stop using your patches without talking to your doctor. If you want to stop your treatment this must be done gradually and your doctor will need to give you a different medicine to control your angina.

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.

All medicines including Cardioplast can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Cardioplast:

- sudden wheeziness
- difficulty in breathing or dizziness
- swelling of the eyelids, face, lips or throat.

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

- Feeling sick (nausea)
- Being sick (vomiting).

Common (may affect up to 1 in 10 people):

- Headache, especially at the start of treatment. You can take some mild pain killers (such as paracetamol) for this (if they continue or are very severe, consult your doctor).

Uncommon (may affect up to 1 in 100 people):

- Redness, itching, burning or irritation of the skin where you have placed the patch (some redness is normal but this should disappear after a short time)
- Inflammation of the skin with symptoms such as red, itchy, scaly skin (contact dermatitis).

Rare (may affect up to 1 in 1,000 people):

- Low blood pressure when standing up, especially when getting up from a sitting or lying position (orthostatic hypotension)
- A fast heart beat or pulse (tachycardia)
- Flushing.

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

- Dizziness.

Not known (frequency cannot be estimated from available data):

- Fast or irregular heart beat called palpitations
- Rash.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6767836
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5. How to store Cardioplast

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

Do not use this medicine after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Return any unused patches to your pharmacist and dispose of the used ones carefully as they may still contain some active medication.

Do not throw away any unused medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help the environment.

6. Contents of the pack and other information

What Cardioplast contains

The active substance is glyceryl trinitrate.

Each Cardioplast 0.2 mg/h transdermal patch contains 20.7 mg of glyceryl trinitrate in a patch size of 7.4 cm², releasing 0.2 mg of glyceryl trinitrate per hour (4.8 mg/24 h).

Each Cardioplast 0.4 mg/h transdermal patch contains 41.4 mg of glyceryl trinitrate in a patch size of 14.8 cm², releasing 0.4 mg of glyceryl trinitrate per hour (9.6 mg/24 h).

Each Cardioplast 0.6 mg/h transdermal patch contains 62.2 mg of glyceryl trinitrate in a patch size of 22.2 cm², releasing 0.6 mg of glyceryl trinitrate per hour (14.4 mg/24 h).

The other ingredients are acrylic adhesive (containing 2-ethylhexylacrylate, vinyl acetate, acrylic acid and aluminium (tris)acetylacetonate), polyolefin film, white printing ink, silicone-coated polyester film.

What Cardioplast looks like and contents of the pack

Cardioplast is a translucent rectangular patch with rounded corners printed with the following:

“Glyceryl trinitrate 0.2 mg/h (5mg/24 h)”

“Glyceryl trinitrate 0.4 mg/h (10mg/24 h)”

“Glyceryl trinitrate 0.6 mg/h (15mg/24 h)”

The patch is covered by a transparent protective liner, which is removed prior to application to expose the sticky back so that it can be stuck onto the skin.

Patches are individually packaged in sachets constructed from Paper/LDPE/Aluminium foil/LDPE film and contained in a cardboard carton, in pack sizes of 7, 10, 15, 28, 30 and 100 transdermal patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland

Manufacturer

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
and
Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Nitroglycerine Jenson 5 10 15 mg/24 h pleisters voor transdermaal gebruik
France:	TRINITRINE MYLAN PHARMA 5 10 15 mg/24 heures, dispositif transdermique
Greece:	Glyceryl Trinitrate / Mylan Transdermal Patch 0.2, 0.4, 0.6 mg/h
Ireland:	Cardioplast
Italy:	Nitroglicerina Mylan
Netherlands:	Nitroglycerine Pleister Mylan 5 10 15 pleister voor transdermaal gebruik 0,2 mg/uur, 0,4 mg/uur , 0,6 mg/uur
Portugal:	Nitroglicerina Mylan
Spain:	Nitroglicerina Mylan 5 mg 10mg 15mg parches transd�ermicos EFG

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