# LYCINATE® TABLETS

glyceryl trinitrate

# **Consumer Medicine Information**

# What is in this leaflet

This leaflet answers some common questions about LYCINATE. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LYCINATE against the benefits this medicine is expected to have for you.

# If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

# What LYCINATE is used for

LYCINATE is used for angina. Angina is a pain or discomfort in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This is usually caused by too little blood and oxygen getting to the heart muscle. The pain of angina is usually brought on by exercise or stress. Other factors may also cause angina. LYCINATE is used to treat an angina attack or to prevent one developing.

LYCINATE belongs to a group of medicines called nitrates. It lets more blood and oxygen reach the heart muscle.

Your doctor may have prescribed this medicine for another reason.

#### Ask your doctor if you have any questions about why LYCINATE has been prescribed for you.

There is no evidence that LYCINATE is addictive or habit forming.

# Before you take it

#### When you must not take it

Do not take LYCINATE if you have ever had an allergic reaction to:

- glyceryl trinitrate, the active ingredient in LYCINATE.
- other medicines containing glyceryl trinitrate- for example skin patches (such as Deponit, Minitran, Nitradisc, Nitro-Dur, Transiderm-Nitro), and sprays (such as Nitrolingual Spray).
- any medicine or food containing nitrates or nitrites.
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hayfever, lumpy rash ("hives") or itching
- fainting

Do not take LYCINATE if you are pregnant, trying to become pregnant or breast-feeding, unless your doctor says you should.

#### Not all heart problems are suitable for treatment with LYCINATE.

Do not take LYCINATE if you have a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM).

- Do not take LYCINATE if you have or have had a head injury.
- Do not take LYCINATE if you have suffered a stroke due to a haemorrhage in the past.
- Do not use LYCINATE if you are taking Phosphodiesterase 5 inhibitors such as sildenafil (Viagra®), tadalafil (Cialis®) and vardenafil (Levitra®)
- Do not take LYCINATE after the expiry date (EXP) printed on the pack, or more than three months after you first open your bottle.

If you take the tablets after the expiry date has passed, they may not work as well.

- Do not take LYCINATE if the packaging is torn or shows any signs of tampering.
- Do not take LYCINATE if the tablets show any visible signs of deterioration (e.g. broken or discoloured).

If you're not sure whether you should be taking LYCINATE, talk to your doctor.

# Before you start to take it

You must tell your doctor if you have:

- an allergy to foods, dyes, preservatives or any other medicines
- poor blood supply to the brain

- a blood condition, such as anaemia (reduced red blood count)
- lung problems
- glaucoma- may be worsened by nitrates
- a recent heart attack- nitrates may lower blood pressure and cause a fast heart beat which may aggravate problems associated with heart attack.
- heart problems as a complication of lung problems
- severe coronary artery problems as a complication of lung problems
- poor liver function
- an overactive thyroid gland (hyperthyroidism)
- any other medical condition.

#### Taking other medicines

Tell your doctor if you are taking or using any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking LYCINATE with other medicines.

#### It is especially important that your doctor knows if you are taking any of the following:

- medicines for high blood pressure
- medicines for heart conditions
- medicines for depression
- tranquillisers/sedatives
- you must not use phosphodiesterase 5 inhibitors such as sildenafil (Viagra®), tadalafil (Cialis®) and vardenafil (Levitra®) if you are taking LYCINATE.

## Use in Children

# Do not give LYCINATE tablets to children.

We do not have enough information on use in children so it is not recommended for that age group.

## Use in Elderly

Elderly patients may be more sensitive to the side effects of LYCINATE tablets. It is advisable to take half a tablet as a starting dose.

# How to take it

The pharmacist's label on the pack will tell you how to take LYCINATE.

If there is something you do not understand, ask your doctor or pharmacist.

# How much to take

At the first sign of an attack, sit down and place 1(one) LYCINATE tablet under your tongue or in your cheek, and allow it to dissolve.

If the Angina is not relieved within 5 minutes, take another dose of Lycinate. You may use up to 2 tablets to relieve the angina pain or discomfort.

If a total of 2 fresh tablets and rest do NOT relieve your angina within 10 minutes, then you should immediately call an ambulance or the nearest hospital.

LYCINATE tablets are scored, so you can break or cut them in half.

You should discuss your overall dose with your doctor.

# How to take it

LYCINATE is absorbed through the lining of your mouth.

# Place your LYCINATE tablet under your tongue, or in your cheek and allow to dissolve.

It will dissolve more easily if your mouth is not dry.

#### DO NOT SWALLOW, CHEW OR CRUSH your LYCINATE tablet, as swallowed LYCINATE tablets are NOT EFFECTIVE.

#### While the tablet is dissolving, avoid any eating, drinking or smoking until the tablet has completely dissolved.

Sometimes you may feel tingling in your mouth when taking LYCINATE. However, the tablet still works even if you do not feel tingling.

## When to take it

# Use LYCINATE tablets at the first symptom of an angina attack.

Your doctor may also advise you to use LYCINATE just before exercise or stressful situations to stop you getting an angina attack.

# How long to take it

After taking LYCINATE, you should get relief of your angina pain or discomfort within a few minutes.

#### When this occurs you may spit out any of the tablet which remains in your mouth to avoid side effect such as headache.

If your angina pain or discomfort is not relieved by a total of 2 fresh LYCINATE tablets within 10 minutes, then you should immediately call an ambulance or nearest hospital.

# If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much LYCINATE, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

# Keep telephone numbers for these places handy.

Too much LYCINATE may cause bluish-coloured lips, fingernails or palms of hands; dizziness or fainting; feeling of extreme pressure in head; shortness of breath.

If you are not sure what to do, contact your doctor or pharmacist.

# While you are taking it

#### Things you must do

# Take LYCINATE exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your attacks of angina.

Always carry your LYCINATE with you.

Tell all doctors, dentists, pharmacists and health professionals involved in your care that you are taking LYCINATE.

Tell your doctor or pharmacist that you are taking LYCINATE if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

**Tell your doctor if, for any reason, you have not taken your tablets exactly as prescribed.** Otherwise, your doctor may think that it was not effective and change

your treatment unnecessarily. Keep a record of the number of angina attacks, when they happen and the possible cause (e.g. during exercise).

Tell your doctor if you continue to have angina attacks or if your angina attacks seem worse when taking LYCINATE.

This helps your doctor give you the best possible treatment.

## Things you must not do

Do not stop taking LYCINATE, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Do not take LYCINATE to treat any other complaints unless your doctor says so.

## Things to be careful of

#### Be careful driving or operating machinery until you know how LYCINATE affects you.

LYCINATE may cause dizziness or faintness in some people. Make sure you know how you react to LYCINATE before you drive a car, operate machinery or do anything else that could be dangerous if you become dizzy or faint.

Get up slowly when getting out of bed or standing up, as you may feel light-headed, dizzy or faint. You may feel light-headed, dizzy or faint after taking LYCINATE. This is because your blood pressure drops. While the medicine is working, it is better for you to sit down and rest for a while. Especially if you are feeling dizzy or faint. Standing up slowly, especially when you get up from lying or sitting, will help your body get used to the change in position and blood pressure.

**Be careful when drinking alcohol while you are taking LYCINATE.** If you drink alcohol whilst taking LYCINATE, your blood pressure may drop, making you feel dizzy or faint.

# Side-Effects

Check with your doctor as soon as possible if you have any problems while taking LYCINATE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, LYCINATE can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most usual side-effects are:

- headache
- low blood pressure, feeling faint or dizzy
- flushing (redness) of the face
- fast heart beat

If you are troubled by a throbbing headache when you take LYCINATE, you may remove the remaining part of the tablet from your mouth once the angina pain is relieved. Ask your doctor or pharmacist to answer any questions you may have.

Rarely reported side-effects are:

- blurred vision
- dry mouth
- severe and prolonged headache
- slow heart beat
- skin rash

Ask your doctor or pharmacist to answer any questions you may have.

If you think you are having an allergic reaction to LYCINATE, tell your doctor immediately or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue
- difficulty in swallowing
- difficulty in breathing
- hay fever
- itching

- lumpy rash ("hives")
- fainting

Tell your doctor or pharmacist immediately if you notice any of the following:

- severe nausea (feeling sick) and vomiting
- swelling of the face
- severe rash, hives, or itching of the skin
- shortness of breath or other breathing problems
- bluish colour of lips, nails or palms of the hands
- severe dizziness or fainting (caused by impaired blood circulation to the brain)
- weak or unusually fast heartbeat
- severe headache
- unusual tiredness or weakness
- restlessness
- worsening of your angina pain

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

# After taking it

# Storage

LYCINATE tablets can easily lose their strength if not stored properly. Glyceryl trinitrate, the active ingredient in LYCINATE tablets, becomes less effective very easily.

 Keep your LYCINATE tablets in a cool, dry and dark place where it stays below 25°C.
Do not carry the tablets close to your body where they become warm.

- Keep your main supply of LYCINATE tablets in the original glass bottle. Always keep the lid tightly closed or your tablets will lose strength more quickly.
- Obtain a fresh supply of LYCINATE within THREE months after you first open the bottle, even if you have not taken all the tablets.
  It is helpful to write the date of opening on the label of the bottle.
- Do not take LYCINATE tablets after the expiry date on the bottle.
- Do not store your LYCINATE tablets mixed with any other tablets.
- Always keep LYCINATE tablets out of reach of children.

A locked cupboard a least one and a half metres above the ground is a good place to store medicines which you do not need to carry.

- Do not store it, or any other medicine, in a bathroom or near a sink. Heat and dampness can destroy some medicines.
- Do not leave LYCINATE in the car or on windowsills. Keep your LYCINATE tablets out of direct sunlight.

# Disposal

If your doctor tells you to stop taking LYCINATE, or the LYCINATE has passed its expiry date, ask your pharmacist what to do with any LYCINATE left over.

# Product description

# What it looks like

LYCINATE tablets are round, flat, white and scored.

Each bottle contains 100 tablets.

# Ingredients

LYCINATE contains 600 microgram of the active ingredient glyceryl trinitrate.

LYCINATE tablets also contain:

- lactose
- dextrin
- maizestarch
- mannitol
- glycerol
- magnesium stearate

#### LYCINATE tablets contain lactose.

LYCINATE : AUST R 227784

# Manufacturer

#### Aspen Pharma Pty Ltd

34-36 Chandos Street St Leonards NSW 2065 Australia

# Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

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