GLYCERYL TRINITRATE WOCKHARDT

glyceryl trinitrate (GLIS-er-ile tri-NITE-rate)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about GLYCERYL TRINITRATE WOCKHARDT (glyceryl trinitrate).

It does not contain all 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 this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

WHAT GLYCERYL TRINITRATE WOCKHARDT IS USED FOR

Glyceryl trinitrate belongs to a group of medicines called nitrates or vasodilators. It relaxes the muscles surrounding blood vessels (arteries and veins) and so helps more blood and oxygen reach the heart. It is also used to control or lower the blood pressure during some surgical procedures.

Your doctor may have prescribed glyceryl trinitrate for another reason. Ask your doctor if you have any questions about why glyceryl trinitrate has been prescribed for you.

Glyceryl trinitrate is not addictive.

This medicine is available only with a doctor's prescription. Glyceryl trinitrate is not recommended for use in children, as there is not enough information on its effects in children.

BEFORE YOU ARE GIVEN GLYCERYL TRINITRATE WOCKHARDT

When you must not be given it

You should not be given GLYCERYL TRINITRATE WOCKHARDT if you have an allergy to glyceryl trinitrate or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- · shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- · rash, itching or hives on the skin

You should not be given glyceryl trinitrate if you have any of the following conditions:

- low blood pressure
- · a recent head injury or stroke
- · swelling around the heart
- reduced red blood cells and iron stores (anaemia) or a lack of oxygen in the blood
- an abnormality of haemoglobin, part of your red blood cells, responsible for carrying oxygen

You should not be given glyceryl trinitrate if you are taking any of the following medicines:

 taking sildenafil, a medicine for impotence • taking riociguat, a medicine for high blood pressure in the lung vessels.

If you are not sure whether you should be given this medicine, talk to your doctor or pharmacist.

Before you start to take it
Tell your doctor if you have allergies to:

- · any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most vasodilator medicines, glyceryl trinitrate is not recommended for use during pregnancy. If there is a need to consider glyceryl trinitrate during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Tell your doctor or pharmacist if you are breast-feeding or intend to breast-feed.

Like most vasodilator medicines, glyceryl trinitrate is not recommended while you are breast-feeding. It is not known if glyceryl trinitrate is excreted into breast-milk.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- · liver disease
- · kidney disease
- a recent heart attack or any heart condition for which you already use a nitrate vasodilator drug such as Anginine® or patches or sprays containing a nitrate
- heart disease caused by poor blood flow in the arteries of the heart
- · any other heart condition
- · any lung condition.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you are given glyceryl trinitrate injection.

Taking other medicines

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

Some medicines and glyceryl trinitrate may interfere with each other. These include:

- · sildenafil, a medicine for impotence
- riociguat, a medicine for high blood pressure in the lung vessels
- alcohol
- aspirin and other nonsteroidal antiinflammatory medicines
- · morphine, a medicine used for pain
- some medicines for depression such as tricyclic antidepressants
- some medicines that block nerve conduction to muscles such as anticholinergics
- heparin, a medicine used to prevent blood clots
- some medicines used to treat high blood pressure
- ergotamine, methysergide and dihydroergotamine; medicines used to prevent or treat migraine headaches

• tranquillisers, medicines used to treat some mental illnesses.

These medicines may be affected by glyceryl trinitrate, or may affect how well it works. You may need different amounts of your medicine, or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being given glyceryl trinitrate.

HOW GLYCERYL TRINITRATE WOCKHARDT IS GIVEN

GLYCERYL TRINITRATE WOCKHARDT given either undiluted or diluted in 5% glucose or 0.9% sodium chloride before use. It should not be mixed with other drugs.

How much is given

Due to variations in the response of individual patients to the drug, the dose of glyceryl trinitrate varies. Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

GLYCERYL TRINITRATE WOCKHARDT is given by slow infusion or 'drip' injection into your veins (intravenously) by either:

- a small volume undiluted solution, or
- · a large volume diluted solution

If you receive too much (overdose)

As GLYCERYL TRINITRATE WOCKHARDT is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects tell your doctor immediately.

Symptoms of a glyceryl trinitrate overdose include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much GLYCERYL TRINITRATE WOCKHARDT. Do this

even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE BEING GIVEN GLYCERYL TRINITRATE WOCKHARDT

Things to be careful of

Be careful driving or operating machinery until you know how glyceryl trinitrate you.

As with other vasodilator medicines, glyceryl trinitrate may cause dizziness, lightheadedness, fainting and headache in some people.

Make sure you know how you react to glyceryl trinitrate before you drive a car,

operate machinery, or do anything else that could be dangerous if you are dizzy or lightheaded. If this occurs do not drive.

If you drink alcohol, dizziness or lightheadedness may be worse.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given glyceryl trinitrate.

Glyceryl trinitrate helps most people with blood pressure problems or heart pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache

These are the more common side effects of glyceryl trinitrate. Mostly these are shortlived.

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

- rapid or irregular heart beat
- nausea, vomiting or abdominal pain
- muscle twitching or restlessness.

These are the less common side effects.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

AFTER USING GLYCERYL TRINITRATE WOCKHARDT

Storage

GLYCERYL TRINITRATE WOCKHARDT will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

PRODUCT DESCRIPTION

What it looks like

GLYCERYL TRINITRATE WOCKHARDT is a clear, practically colourless solution.

Ingredients

Active ingredients:

glyceryl trinitrate 50 mg/50 mL

Other ingredients:

- glucose
- glucose monohydrate
- propylene glycol
- Water for Injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo

Sponsor/Distributor

Wockhardt Bio Pty Limited Suite 103 39 East Esplanade

Manly NSW 2095 Australia Distributor:

InterPharma Pty Ltd Suite 103

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Australian Register Numbers

GLYCERYL TRINITRATE WOCKHARDT

is available in 50 mg in 50 mL glass vials.

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