

## PATIENT INFORMATION LEAFLET FOR TRINRALIN 10, 25, 50 & 100

### SCHEDULING STATUS

S3

### TRINRALIN

#### (Hydralazine hydrochloride 10 / 25 / 50 / 100 mg, tablets)

**Contains sugar** – Lactose anhydrous, mannitol

TRINRALIN 10: Contains 82,62 mg mannitol.

TRINRALIN 25: Contains 140,07 mg lactose anhydrous.

TRINRALIN 50: Contains 280,14 mg lactose anhydrous.

TRINRALIN 100: Contains 314,30 mg lactose anhydrous.

### Read all of this leaflet carefully before you start taking TRINRALIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRINRALIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

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

## **1. What TRINRALIN is and what it is used for**

Hydralazine hydrochloride belongs to a group of medicines called antihypertensives.

Hydralazine is used to treat high blood pressure.

It works by relaxing blood vessels and increasing the supply of blood and oxygen to the heart.

## **2. What you need to know before you take TRINRALIN**

### **Do not take TRINRALIN:**

- if you are hypersensitive (allergic) to hydralazine or any of the other ingredients of TRINRALIN
- if you suffer from severe tachycardia (fast heart beat) or right sided heart failure due to increased pressure in the blood vessels of the lungs
- if your heart function is impaired or if you have blockage of one or more arteries that supply blood to the heart (coronary heart disease)

### **Warnings and precautions**

#### **Special care should be taken with TRINRALIN:**

- If you have or have ever had a condition called Systemic Lupus Erythematosus (SLE), an autoimmune condition which causes joint pain, skin rashes and fever
- If you have been told you are a slow acetylator (this means that your body handles some medicines more slowly than other people) or if you are a woman
- If you will receive sedation (anaesthesia) care should be taken because you can suffer from low blood pressure (hypotension)
- If you have had a heart attack or suffer from angina pectoris, which causes pain in the chest with exercise
- If you suffer from any serious liver or kidney problems
- If you have cerebrovascular disease (narrowing of the blood vessels in the brain)

- If you are taking antidepressant medication.

Your doctor may send you to undergo some laboratory tests to determine your blood count. This is important to determine if you may develop joint stiffness, fever, chest pain, continued feelings of discomfort or other unexplained signs of symptoms.

### **Other medicines and TRINRALIN**

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

TRINRALIN could interact with other medicines and the dosages of the medicines might have to be changed by your doctor as the amounts of TRINRALIN or other medicines in your blood may be affected.

It is important to tell your doctor if you are taking any of the following medicine:

- Medicines for high blood pressure, ACE inhibitors, beta-blockers, calcium channel blockers, vasodilators
- Medicines for water retention
- Medicine for depression, including monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants
- Medicine to control pain and inflammation
- Medicine to control psychoses
- Medicine called nitrates that helps to lower blood pressure or that causes a depression of your nervous system (including alcohol).

If you are going to have general anaesthetic you should tell your doctor or dentist that you are taking TRINRALIN.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a

baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine

### **Driving and using machines**

It is not always possible to predict to what extent TRINRALIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TRINRALIN affects them.

### **Important information about some of the ingredients of TRINRALIN**

**TRINRALIN** contains lactose. If you have been told that you have an intolerance to some sugars, you should not take TRINRALIN.

### **3. How to take TRINRALIN**

Do not share medicines prescribed for you with any other person.

Always take TRINRALIN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 100 – 200 mg per day, starting with 10 mg or 20 mg two to four times daily. This is increased gradually until the desired effect is obtained or unacceptable side effects develop. The dose should not exceed 300 mg per day.

Your doctor will tell you how long your treatment with [PRODUCT NAME] will last. If you have the impression that the effect of TRINRALIN is too strong or too weak, tell your doctor or pharmacist.

### **If you take more TRINRALIN than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you forget to take use TRINRALIN**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take TRINRALIN at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

### **4. Possible side effects**

TRINRALIN can have side effects.

Not all side effects reported for TRINRALIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRINRALIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking TRINRALIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRINRALIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin and whites of the eyes, which may indicate problems with the liver such as jaundice and hepatitis

- Kidney failure (e.g. changes in urine, swelling of legs, ankles or feet, shortness of breath, tiredness and nausea)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- abnormal or an unusually fast heartbeat (palpitations)
- severe headaches
- sweating
- anorexia
- blocked nose (nasal congestion)
- upset stomach (gastrointestinal disturbances)
- feeling sick (nausea)
- throwing up (vomiting)
- loose stools (diarrhoea)

*Less frequent side effects:*

- feeling of numbness, prickling or tingling in your feet or hands (peripheral neuritis)
- muscle cramps,
- chills
- fever
- psychotic reactions characterised by depression, and feeling mentally confused (disorientation)
- chest pains, breathlessness, anxiety, restlessness
- skin rash
- swelling and/or pain in joints, muscle pain
- low blood pressure, dizziness

- flushing
- watery or sore itchy eyes
- loss of appetite, weight loss

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TRINRALIN.

## **5. How to store TRINRALIN**

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect product from moisture and light.

Store in the original package.

Keep the container tightly closed.

Do not use after the expiry date stated on the carton/label.

Return all unused medicines to the pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

## **6. Contents of the pack and other information**

### **What TRINRALIN contains**

- The active substance is hydralazine hydrochloride
- The other ingredients are lactose anhydrous, microcrystalline cellulose, sodium starch

glycolate, stearic acid, sunset yellow lake, and mannitol and magnesium stearate (for 10 mg only).

**What TRINRALIN looks like and contents of the pack**

**TRINRALIN 10:** Orange coloured, circular, biconvex tablets, debossed "10" on one side and plain on other side.

**TRINRALIN 25:** Orange coloured, circular, flat bevel edged tablets, debossed '25' on one side and plain on other side.

**TRINRALIN 50:** Orange coloured, circular, flat bevel edged tablets, debossed '50' on one side and plain on other side.

**TRINRALIN 100:** Orange coloured, circular, flat bevel edged tablets, debossed '100' on one side and plain on other side.

100, 500 or 1000 tablets packed in white, opaque HDPE container with a white, opaque polypropylene closure and a cotton coil filler.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Strides Pharma SA (Pty) Ltd

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Midrand

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**This leaflet was last revised in**

**Registration/Application number**

**TRINLANIN 10: 55/7.1.3/0890.889**

**TRINLANIN 25: 54/7.1.3/0820.817**

**TRINLANIN 50: 54/7.1.3/0821.818**

**TRINLANIN 100: 54/7.1.3/0822.819**

**Access to the corresponding Professional Information**

To follow