#### **SCHEDULING STATUS**

S2

#### 1. NAME OF THE MEDICINE

DYNA PENTOXIFYLLINE 400 mg SR, film coated tablet

DYNA PENTOXIFYLLINE 400 mg SR contains sugar (lactose 31,34 mg)

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

#### PENTOXIFYLLINE 400 mg SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor,
   pharmacist, nurse or other healthcare provider.
- DYNA PENTOXIFYLLINE 400 mg SR 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 DYNA PENTOXIFYLLINE 400 mg SR is and what it is used for
- 2. What you need to know before you use DYNA PENTOXIFYLLINE 400 mg SR
- 3. How to use DYNA PENTOXIFYLLINE 400 mg SR
- Possible side effects
- How to store DYNA PENTOXIFYLLINE 400 mg SR
- 6. Contents of the pack and other information

### 1. What DYNA PENTOXIFYLLINE 400 mg SR is and what it is used for

DYNA PENTOXIFYLLINE 400 mg SR belongs to a group of medicines called peripheral vasodilators. It works by increasing the blood flow to the arms and legs.

### DYNA PENTOXIFYLLINE 400 mg SR can be used to treat:

- Peripheral vascular disease (poor circulation to the arms and legs including ulcers).
- The symptoms of intermittent claudication (pain when walking or when at rest, caused by poor circulation to the legs).
- The symptoms of Raynaud's syndrome (pain in the fingers caused by artery spasms).

# 2. What you need to know before you take DYNA PENTOXIFYLLINE 400 mg SR Do not take DYNA PENTOXIFYLLINE 400 mg SR:

- if you are hypersensitive (allergic) to pentoxifylline or other methyl xanthine medicines,
   or to any of the ingredients of DYNA PENTOXIFYLLINE 400 mg SR (see section 5)
- if you have heart problems or have recently had a heart attack
- if you have severe palpitations (very fast and uneven heartbeats)
- if you have had a stroke with bleeding in the brain (cerebral haemorrhage)
- if you have had bleeding in the eye (retinal haemorrhage)
- if you are pregnant or breastfeeding your baby
- if you have porphyria (a rare hereditary disease affecting the blood pigment with symptoms such as dark urine and extreme sensitivity of the skin to light).

Warnings and precautions

### Take special care with DYNA PENTOXIFYLLINE 400 mg SR:

- if you feel dizzy, light-headed or faint when you stand or sit up too quickly (low blood pressure)
- if you are on medication for high blood pressure
- if you have problems with the blood supply to your heart caused by hardening or narrowing of the arteries
- if you are prone to increased bleeding and you are using blood clotting medication
- if you have liver or kidney problems
- if you have diabetes and use insulin for this condition.

## Other medicines and DYNA PENTOXIFYLLINE 400 mg SR

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

Medicines that may interact with DYNA PENTOXIFYLLINE 400 mg SR:

- Medicines for diabetes including tablets or insulin (high doses of DYNA
   PENTOXIFYLLINE 400 mg SR may enhance the effects of these medicines).
- Medicines for high blood pressure (DYNA PENTOXIFYLLINE 400 mg SR may increase the effect of these medicines).
- Anticoagulants such as warfarin (medicine used to thin your blood).
- Ketorolac or meloxicam (anti-inflammatory medicines used for pain relief as there is an increased risk of bleeding and/or the time it takes for blood to clot).
- Theophylline used to treat wheezing or difficulty in breathing (blood levels of theophylline may increase leading to an increase in the side effects of theophylline).
- Cimetidine (anti-histamine) as this may make the effect of DYNA PENTOXIFYLLINE

400 mg SR stronger.

#### DYNA PENTOXIFYLLINE 400 mg SR with food and drink

DYNA PENTOXIFYLLINE 400 mg SR should be taken after meals, swallowed whole with sufficient amounts of liquid (approximately half a glass).

## Pregnancy, breastfeeding and fertility

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 health care provider for advice before using DYNA PENTOXIFYLLINE 400 mg SR.

Do not take **DYNA PENTOXIFYLLINE 400 mg SR** if you are pregnant or breastfeeding your baby.

## **Driving and using machines:**

DYNA PENTOXIFYLLINE 400 mg SR can cause dizziness.

It is not always possible to predict to what extent DYNA PENTOXIFYLLINE 400 mg SR 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 DYNA PENTOXIFYLLINE 400 mg SR affects them.

# DYNA PENTOXIFYLLINE 400 mg SR contains lactose

DYNA PENTOXIFYLLINE 400 mg SR contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take DYNA PENTOXIFYLLINE

400 mg SR.

DYNA PENTOXIFYLLINE 400 mg SR contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

### 3. How to take DYNA PENTOXIFYLLINE 400 mg SR

Do not share medicines prescribed for you with any other person. Always use DYNA PENTOXIFYLLINE 400 mg SR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one **DYNA PENTOXIFYLLINE 400 mg SR** tablet taken two to three times daily after meals, swallowed whole with sufficient amounts of liquid (approximately half a glass).

Children:

DYNA PENTOXIFYLLINE 400 mg SR is not suitable for use in children.

Your doctor will tell you how long your treatment with DYNA PENTOXIFYLLINE 400 mg SR will last. Do not stop treatment early because your symptoms may return. If you have the impression that the effect of DYNA PENTOXIFYLLINE 400 mg SR is too strong or too weak, tell your doctor or pharmacist.

#### If you take more DYNA PENTOXIFYLLINE 400 mg SR than you should:

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

Symptoms of overdose may include:

 fever, faintness, flushing, hypotension (low blood pressure), drowsiness, feeling agitated and seizures (fits).

### If you forget to take DYNA PENTOXIFYLLINE 400 mg SR:

If you forget to take a DYNA PENTOXIFYLLINE 400 mg SR tablet, take as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

## If you stop taking DYNA PENTOXIFYLLINE 400 mg SR

Keep taking DYNA PENTOXIFYLLINE 400 mg SR until your doctor tells you to stop taking it.

### 4. Possible side effects

Not all side effects reported for DYNA PENTOXIFYLLINE 400 mg SR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNA PENTOXIFYLLINE 400 mg SR, please consult your healthcare provider for advice.

If any of the following happens, stop using DYNA PENTOXIFYLLINE 400 mg SR 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DYNA PENTOXIFYLLINE 400 mg SR. 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:

- you bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- increased or fast heart beat (tachycardia), irregular or rapid heartbeat accompanied with shortness of breath (palpitations)
- chest pain accompanied with pain in your arms, neck, jaw, shoulder or back (angina)
- painful headache, mental confusion, fever, chills, loss of appetite (aseptic meningitis),
   heavy bleeding (haemorrhage)
- malaise or fatigue, clay coloured or white stools, dark coloured urine, inability to digest certain foods, you feel tired, sick and have no appetite.
- increased liver enzymes (with symptoms such as abdominal pain, dark urine, fatigue,
   fever, jaundiced skin and eyes, joint and muscle pain a loss of appetite, 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:

nausea, localised pain below the ribs, vomiting, diarrhoea, stomach discomfort,
 bloating, feeling of fullness

Less frequent side effects:

- feeling agitated, sleep disturbances
- dizziness, headache, fever, chills, body ache
- low blood pressure
- difficulty breathing because the airways have narrowed, coughing, wheezing,
   tightness or pressure in the chest
- flushing of the skin, hot flushes, red or white patches on the skin that vary in size and shape, inflammation of the skin, itchy skin.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reporting Form", found online under SAHPRA's publications:

<a href="https://www.sahpra.org.za/Publications/Index/8">https://www.sahpra.org.za/Publications/Index/8</a>. By reporting side effects, you can help provide more information on the safety of DYNA PENTOXIFYLLINE 400 mg SR.

#### 5. How to store DYNA PENTOXIFYLLINE 400 mg SR

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the container well closed.

Keep blisters in carton until required for use.

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

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).