PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

NAME OF THE MEDICINE

DYNA PENTOXIFYLLINE 400 mg SR film coated tablet

Pentoxifylline

DYNA PENTOXIFYLLINE 400 mg SR contains sugar (lactose monohydrate 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

PROPOSED PATIENT INFORMATION LEAFLET

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)
- symptoms of intermittent claudication (pain when walking or when at rest, caused by poor circulation to the legs)
- symptoms of Raynaud's syndrome (pain in the fingers caused by artery spasms).

2. What you need to know before you take/use DYNA PENTOXIFYLLINE 400 mg SR

Do not take/use 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 (listed in section [~~5~~] 6)
- 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

Should you experience symptoms an allergic reaction (a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue), stop taking DYNA PENTOXIFYLLINE 400 mg SR and immediately inform your doctor.

- 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 all 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)
- anticoagulants such as warfarin (medicine used to thin your blood)

- medicines for high blood pressure (DYNA PENTOXIFYLLINE 400 mg SR may increase the effect of these medicines)
- 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 (antihistamine), as this may make the effect of DYNA PENTOXIFYLLINE 400 mg SR stronger
- ciprofloxacin used to treat bacterial infections may make the effect of DYNA PENTOXIFYLLINE 400 mg SR stronger
- there is an increased risk of bleeding when DYNA PENTOXIFYLLINE 400 mg SR is taken with medicines used to stop blood clots from forming (such as clopidogrel, eptifibatide, tirofiban, epoprostenol, iloprost, abciximab, anagrelide, ticlopidine, dipyridamole) and medicines used to relieve pain, reduce inflammation, and bring down a high temperature.

DYNA PENTOXIFYLLINE 400 mg SR with food and drink

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare 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/use 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.

Adults:

The usual dose is one DYNA PENTOXIFYLLINE 400 mg SR film coated 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/use 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, nausea, dizziness, irregular or rapid heartbeat, hypotension (low blood pressure), drowsiness, feeling agitated and seizures (fits).

If you forget to take/use DYNA PENTOXIFYLLINE 400 mg SR

If you forget to take DYNA PENTOXIFYLLINE 400 mg SR, take as soon as you remember

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

If you stop taking/using 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

DYNA PENTOXIFYLLINE 400 mg SR can have 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 taking/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.

The following side effects have been reported but the frequency for them to occur is not known:

- a low level of white blood cells in the blood, which can interfere with the ability to fight infection
- producing more saliva than usual
- rash.

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. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DYNA PENTOXIFYLLINE 400 MG SR.

You can also send an email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

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).

6. Contents of the pack and other information

What DYNA PENTOXIFYLLINE 400 mg SR contains

- The active ingredient is pentoxifylline.

Each DYNA PENTOXIFYLLINE 400 mg SR film coated tablet contains 400 mg pentoxifylline.

- The other ingredients are:

Tablet cores:

Carnauba wax, cellulose acetate, hypromellose, lactose monohydrate, magnesium stearate, purified stearic acid

Film coating:

Cellulose acetate, triacetin and Opadry II pink Y30-14132-AD
(consisting of erythrosine dye (E127), hydroxypropylmethylcellulose, indigo carmine lake (E132), lactose monohydrate, titanium dioxide (E171), triacetin)

What DYNA PENTOXIFYLLINE 400 mg SR looks like and contents of the pack

DYNA PENTOXIFYLLINE 400 mg SR: Pink, oval film coated tablets.

DYNA PENTOXIFYLLINE 400 mg SR tablets are available in:
White polypropylene securitainer with a white polyethylene tear-tab cap, a foam insert and silica gel sachet containing 30 or 100 tablets.
Carton containing 30 or 100 tablets in blisters. Each blister comprises of white opaque PVC film coated with PVDC / Aluminium foil coated with PVDC.
Not all pack types and sizes are marketed.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd
1st Floor, Grapevine House, Steenberg Office Park

PROPOSED PATIENT INFORMATION LEAFLET

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

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