SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DYNA BEZAFIBRATE 400 SR (slow release tablets)

Read this entire leaflet carefully before you start taking DYNA BEZAFIBRATE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DYNA BEZAFIBRATE** 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.

1. WHAT DYNA BEZAFIBRATE CONTAINS:

Active ingredient:

Each slow release tablet contains 400 mg bezafibrate.

Inactive ingredients:

Hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol, polyethylene oxide, silica colloidal anhydrous, talc, titanium dioxide.

2. WHAT DYNA BEZAFIBRATE IS USED FOR:

DYNA BEZAFIBRATE is used to lower cholesterol.

3. BEFORE YOU TAKE DYNA BEZAFIBRATE:

Do not take DYNA BEZAFIBRATE:

- If you are hypersensitive (allergic) to bezafibrate, or any of the ingredients of **DYNA BEZAFIBRATE** (see **WHAT DYNA BEZAFIBRATE CONTAINS**)

- If you have severe liver or kidney disease
- If you suffer from gallstone or gallbladder disorders
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**)

Take special care with DYNA BEZAFIBRATE:

- If you take medicine that prevents blood clotting
- If you are diabetic
- If you take tolbutamide (to lower blood sugar levels), phenytoin (to treat epilepsy or furosemide (water tablet)
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**)
- If you develop muscle pain, tenderness or weakness, stop taking **DYNA BEZAFIBRATE** and consult your doctor

Taking DYNA BEZAFIBRATE with food and drink

DYNA BEZAFIBRATE must be swallowed whole, with a little fluid, after the evening meal.

Pregnancy and breastfeeding:

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **DYNA BEZAFIBRATE.** You should not be taking **DYNA BEZAFIBRATE** if you are pregnant or breastfeeding your baby (see **Do not take DYNA BEZAFIBRATE**).

Driving and using machines:

DYNA BEZAFIBRATE may cause dizziness with some individuals which could affect the ability to drive and operate machinery. Do not drive or operate any machinery before you know how **DYNA BEZAFIBRATE** affects you.

Taking other medicines with DYNA BEZAFIBRATE:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please inform your doctor or pharmacist if you are taking or have taken any of the following:

- Cholestyramine (used to reduce cholesterol) is to be taken 2 hours apart from **DYNA BEZAFIBRATE,** to prevent **DYNA BEZAFIBRATE** from not being absorbed properly
- Medicine to prevent blood from clotting, such as warfarin, as the dosage may have to be reduced
- Antidiabetic medication, as **DYNA BEZAFIBRATE** may potentiate the effect of this medication
- Medicines called MAO-inhibitors (a type of antidepressant) as it may affect your liver if used together with **DYNA BEZAFIBRATE**

4. HOW TO TAKE DYNA BEZAFIBRATE:

Always take **DYNA BEZAFIBRATE** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of **DYNA BEZAFIBRATE** is too strong or too weak, talk to your doctor or pharmacist.

It is important to follow a proper diet as prescribed by your doctor to assist with lowering your cholesterol. Your doctor will monitor your progress regularly over the first 8 weeks of treatment to determine whether **DYNA BEZAFIBRATE** works properly for you.

The usual dose is one tablet taken in the evening, or as determined by your doctor. The tablet must be swallowed whole, with a little fluid, after the evening meal.

If you take more DYNA BEZAFIBRATE 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 be include stomach pain, nausea and vomiting

If you forget to take DYNA BEZAFIBRATE:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

DYNA BEZAFIBRATE can have side effects. Not all side effects reported for **DYNA BEZAFIBRATE** are included in this leaflet. Should your general health worsen while taking **DYNA BEZAFIBRATE**, please consult your doctor, pharmacist or other health care professional for advice.

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

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in 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 BEZAFIBRATE**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Nausea, vomiting, diarrhoea
- Indigestion, flatulence, stomach discomfort
- Weight gain, headache
- Dizziness, fatigue or drowsiness
- Skin rash, itchiness

- Hair loss
- Blood disorders
- Feeling anxious or nervous
- Unable to perform sexually

6. STORING AND DISPOSING OF DYNA BEZAFIBRATE:

- Store at or below 25 °C.
- Protect from light.
- Keep the blisters in the carton until required for use.
- **KEEP OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the container or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF DYNA BEZAFIBRATE:

White polypropylene securitainer with a white polyethylene snap-on-cap containing 30 or 100 tablets.

Carton containing 30 or 100 tablets in blisters. Each blister is comprised of white opaque PVC/PVDC film/Aluminium foil and contains 10 tablets.

8. IDENTIFICATION OF DYNA BEZAFIBRATE:

White, round, bi-convex, film coated tablet marked “400” on one side.

9. REGISTRATION NUMBERS:

RSA S3 36/7.5/0280

NAM NS2 087/7.5/0182

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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