

Please read this leaflet carefully before taking DYNATOR tablets.

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

Scheduling Status: Schedule 4

Proprietary name, Strength and Pharmaceutical Form:

DYNATOR 10 mg (film coated tablet)

DYNATOR 20 mg (film coated tablet)

DYNATOR 40 mg (film coated tablet)

DYNATOR 80 mg (film coated tablet)

1. WHAT DYNATOR CONTAINS

Active ingredient:

Each **DYNATOR** tablet contains atorvastatin calcium equivalent to 10, 20, 40 or 80 mg atorvastatin respectively.

Inactive ingredient:

Each **DYNATOR** tablet contains the following inactive ingredients:

butylhydroxyanisole (as a preservative) (0,02 % w/w), crospovidone, ethanol, lactose monohydrate, magnesium stearate, Opadry OYL-28900 white, Prosolv SMCC 90, Sinespum C, sodium hydrogen carbonate and sodium lauryl sulphate.

DYNATOR tablets contain lactose monohydrate and sucrose (forms of sugar).

2. WHAT DYNATOR IS USED FOR

DYNATOR is used to lower the cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can also raise your HDL-C ("good" cholesterol). **DYNATOR** is prescribed if your cholesterol is not lowered enough with exercise and a low-fat diet alone.

3. BEFORE YOU TAKE DYNATOR

Do not take DYNATOR:

- If you are hypersensitive (allergic) to any of the ingredients of **DYNATOR** (see "**WHAT DYNATOR CONTAINS**").
- If you have an acute or chronic liver disease.
- **If you are pregnant, planning to become pregnant or breastfeeding.**

DYNATOR is not indicated for the use in children as safety and efficacy has not been established.

- If you are using rifampicin, diltiazem or have a habit of consuming large amounts of grapefruit.

Take special care with DYNATOR:

- If you are taking large amounts of alcohol.
- If your liver or kidney function is impaired.
- If you are suffering from a severe infection.
- If you are recovering from major surgery or trauma.

- If you have uncontrolled seizures (convulsions).
- If you just had an organ transplant with therapy to prevent transplant rejection.
- Before having any surgery (including dental surgery), tell your doctor or dentist in charge that you are taking **DYNATOR**.

Taking DYNATOR with food or drink:

Drinking too much alcohol may change the way **DYNATOR** affects your body. You should not drink alcoholic beverages on a daily basis or take more than 1 or 2 drinks at any time. Before prescribing medicines to lower your cholesterol, your doctor will probably try to control your cholesterol by prescribing a personal diet for you. Such a diet will be lower in total fat, particularly saturated fat, and dietary cholesterol. **DYNATOR** will only be effective when a scheduled diet is properly followed. **DYNATOR** can be taken with or without meals.

Pregnancy and breastfeeding:

Do not take **DYNATOR** if you are pregnant, planning to become pregnant or breastfeeding. Please consult your doctor.

Driving and using machinery:

Do not operate machinery or drive a vehicle until you know how **DYNATOR** affects you, as these tablets may cause nausea, headache and dizziness.

Using other medicines with DYNATOR:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DYNATOR** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

DYNATOR may interact with the following medication:

- Cyclosporin (medicine used after organ transplant)
- Itraconazole or ketoconazole (antifungal treatment)
- Erythromycin and clarithromycin (antibiotics)
- HIV protease inhibitors (such as indinavir or ritonavir)
- Niacin (Vitamin B3)
- Fibrates (other medicines that also inhibits / reduces cholesterol levels)
- Digoxin (heart medicine)
- Warfarin (medicine that prevent the blood from forming clots)
- Cholestyramine (medicine to treat high cholesterol or diarrhoea).
- Cimetidine (used for heartburn or stomach ulcers).
- Oral contraceptives.
- Rifampicin
- Diltiazem
- Taking grapefruit may also interact with **DYNATOR**

Not all the medicines that may interact with DYNATOR are listed above. Please tell your doctor, pharmacist or health care professional about all the medicines you are taking before you start taking DYNATOR.

4. HOW TO USE DYNATOR

Always take **DYNATOR** 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 **DYNATOR** is too strong or too weak, talk to your doctor or pharmacist.

- ♦ **The dosage will be different for different patients.**
- ♦ **Your doctor will know the correct dosage for your specific needs.**
- ♦ **Never take more or less than your recommended dose.**
- ♦ **Do not take it more often, and do not take it for longer periods than your doctor directed.**

Adult dose:

The tablets can be taken with or without meals.

The usual starting is 10 mg in the evening.

Your doctor can increase your dosage to a maximum of 80 mg daily.

When you use **DYNATOR** along with Cholestyramine, the **DYNATOR** should be taken 1 hour before or 4 hours after cholestyramine. The score on the tablet is intended for dose division.

If you take more DYNATOR than you should:

In the event of an over dose, contact your doctor or pharmacist. If neither is available go to the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take DYNATOR:

If you miss a dose, take it as soon as you remember. Do not take **DYNATOR** if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of **DYNATOR** at the same time.

5. POSSIBLE SIDE EFFECTS

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

The following side effects have been reported:

- Depression
- Headache
- Dizziness
- Irregular heartbeat

- Diarrhoea, abdominal pain, constipation, flatulence
- Nausea, vomiting
- Chest pain
- Low blood sugar, high blood sugar, weight gain, anorexia, increased appetite
- Inflammation of the liver
- Rash, Stevens-Johnson syndrome, tissue damage
- Hair loss
- Vascular disorders
- Allergic reactions (including anaphylaxis)
- Tendon rupture
- Sinusitis
- Asthma, bronchitis, shortness of breath
- Ringing in the ears, deafness
- Lazy eye, dry eyes, sensitivity to light
- Urinary disorders
- Infection
- Flu-like symptoms
- Tiredness and sleeplessness
- Memory loss

6. STORING AND DISPOSING OF DYNATOR

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

7. PRESENTATION OF DYNATOR

DYNATOR tablets are packed into silver, hard aluminium / aluminium blister strips of 3 x 10 tablets inside an outer cardboard box.

8. IDENTIFICATION OF DYNATOR

- DYNATOR 10 mg:** Cylindrical, biconvex, coated, scored white tablets on one side and with the code, AT1 on the other side.
- DYNATOR 20 mg:** Cylindrical, biconvex, coated, scored white tablets on one side and with the code, AT2 on the other side.
- DYNATOR 40 mg:** Cylindrical, biconvex, coated, scored white tablets on one side and with the code, AT4 on the other side.
- DYNATOR 80 mg:** Oblong, biconvex, coated, scored white tablets on one side and with the code, AT8 on the other side.

9. REGISTRATION NUMBER

DYNATOR 10 mg : 43/7.5/0167

DYNATOR 20 mg : 43/7.5/0168

DYNATOR 40 mg : 43/7.5/0169

DYNATOR 80 mg : 43/7.5/0170

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pharma Dynamics (Pty) Ltd.

2nd Floor Grapevine House

Steenberg Office Park

Westlake, 7945

11. DATE OF PUBLICATION

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