

**PROPOSED PATIENT INFORMATION LEAFLET for
DYNAVAL CO 80/12,5, 160/12,5 and 160/25**

Read all of this leaflet carefully before you start taking DYNAVAL CO.

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

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DYNAVAL CO 80/12,5 film coated tablets

DYNAVAL CO 160/12,5 film coated tablets

DYNAVAL CO 160/25 film coated tablets

1. WHAT DYNAVAL CO CONTAINS

Active ingredients:

DYNAVAL CO 80/12,5:

Each film coated tablet contains 80 mg valsartan and 12,5 mg hydrochlorothiazide.

DYNAVAL CO 160/12,5:

Each film coated tablet contains 160 mg valsartan and 12,5 mg hydrochlorothiazide.

DYNAVAL CO 160/25:

Each film coated tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide.

Other ingredients:

Colloidal anhydrous silica, colloidal silicon dioxide, crospovidone, magnesium carbonate, microcrystalline cellulose, povidone, pregelatinised starch, sodium lauryl sulphate, sodium stearyl

fumarate and sorbitol powder.

The following colourants are also included; iron oxide brown (160/12,5 mg and 160/25 mg tablets), iron oxide red (80/12,5 mg and 160/12,5 mg tablets), iron oxide yellow (160/25 mg tablets) and opadry white (containing lactose monohydrate, hypromellose, titanium dioxide and macrogol 4000).

DYNAVAL CO tablets contain lactose (see "**BEFORE YOU TAKE DYNAVAL CO**").

2. WHAT DYNAVAL CO IS USED FOR

DYNAVAL CO is used to treat mild to moderate high blood pressure.

3. BEFORE YOU TAKE DYNAVAL CO

Do not take DYNAVAL CO if:

- you are allergic (hypersensitive) to any of the ingredients of **DYNAVAL CO** (see "**WHAT DYNAVAL CO CONTAINS**").
- after previously taking other angiotensin receptor blockers (ARBs) or ACE inhibitors you have experienced swelling of your face, lips, eye lids, mouth, tongue or throat. You must never take these medicines, including **DYNAVAL CO**, again.
- you suffer from heart disease, including a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM).
- you suffer from a severe kidney disorder.
- you are currently taking lithium.
- you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride.
- you suffer from porphyria (a rare blood disorder).
- you are pregnant or breast-feeding (see "**Pregnancy and Breast-feeding**").

Take special care with DYNAVAL CO:

- **Should you become pregnant while taking DYNAVAL CO, stop taking the tablets immediately and contact your doctor. A switch to a different treatment should be carried out before a planned pregnancy.**
- If you are on a low-salt diet, have lost a lot of fluids recently (due to excessive sweating, diarrhoea, vomiting, dialysis) or are taking high doses of water tablets.
- If you take salt substitutes containing potassium or you have high potassium levels in your blood.
- If you suffer from the symptoms of low blood pressure e.g. feeling dizzy when standing up.
- If you have a kidney disorder.
- If you have a liver disorder.
- If you have a heart disease or have had a heart attack.
- If you have diabetes and are being treated for it.
- If you have gout. **DYNAVAL CO** may worsen your gout.
- If you have systemic lupus erythematosus (also called “lupus” or “SLE”). (Symptoms include pain in the joints or weakness in the muscles.)

The first dose may cause a bigger fall in blood pressure than the following doses. You may notice this as a feeling of weakness or dizziness, and it may help to lie down. Contact your doctor if you are worried. In order to prevent an extreme fall in blood pressure with the first dose, existing therapy with diuretics (“water tablets”) should be discontinued 2 to 3 days before taking **DYNAVAL CO**. Your doctor should check the electrolyte content of your blood thereafter.

Taking DYNAVAL CO with food and drink:

DYNAVAL CO is best taken every morning at the same time. **DYNAVAL CO** tablets can be taken with or without food.

Pregnancy and Breast-feeding:

Do not take **DYNAVAL CO** if you are pregnant, planning to become pregnant or think you may be pregnant. If you become pregnant, please contact your doctor or healthcare professional immediately.

Do not take **DYNAVAL CO** if you are breast-feeding.

Driving and using machinery:

DYNAVAL CO may cause some people to become dizzy or tired.

Do not drive a vehicle or operate any machinery before you know how **DYNAVAL CO** affects you.

Important information about some of the ingredients of DYNAVAL CO:

DYNAVAL CO contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **DYNAVAL CO**.

Taking other medicines with DYNAVAL CO:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DYNAVAL CO** with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or healthcare professional for advice.

The following medicines may interact with **DYNAVAL CO**.

- Diuretics (“water tablets”) or other blood pressure lowering medicines.
- Indomethacin, allopurinol or other anti-inflammatory medicines for the treatment of gout or muscular pain.
- Lithium (used in the treatment of mood disorders) (see “**Do not take DYNAVAL CO**”).
- Medicines used to treat high blood sugar (diabetes), including insulin.

- Potassium supplements or products containing potassium. This may include your daily multivitamin supplement.
- Vitamin D supplements or calcium salts.
- Alcohol, narcotics or any other medicines that work on the nervous system.
- Amantadine and biperiden (used to treat Parkinson's disease).
- Diazoxide (used to treat diabetes).
- Cytotoxic medicines (e.g. cyclophosphamide, methotrexate) used to treat cancer.
- Anticholinergic agents (e.g. atropine,) pressor amines (e.g. epinephrine) and methyldopa used to treat heart disease.
- Cholestyramine (used to treat high cholesterol).
- Kaliuretic diuretics.
- Corticosteroids, amphotericin, penicillin G and salicylic acid derivatives (used to treat infections and inflammations).
- ACTH (used during eye surgery).
- Carbenoxolone (used to treat ulcers).

Not all medicines that may interact with DYNAVAL CO are listed above. Consult your doctor or pharmacist if you are unsure about any medicines.

4. HOW TO TAKE DYNAVAL CO

Always take **DYNAVAL CO** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The tablets should be swallowed with a glass of water or juice.

It is recommended to take the tablets at the same time every day.

The recommended dose of **DYNAVAL CO** is 1 tablet once a day. The maximum effect of **DYNAVAL CO** is usually seen within 2 to 4 weeks.

If you think the effects of **DYNAVAL CO** are too strong or too weak for you, talk to your doctor or

pharmacist.

If you take more DYNAVAL CO than you should:

If you accidentally take more **DYNAVAL CO** than recommended, contact your doctor or pharmacist immediately. If neither is available, seek help at 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 your DYNAVAL CO:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. **Do not take a double dose.**

5. POSSIBLE SIDE-EFFECTS

DYNAVAL CO can have side-effects. Not all side-effects reported for **DYNAVAL CO** are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop taking DYNAVAL CO and contact your doctor or healthcare professional immediately:

- swelling of the face, hands, feet or ankles, lips, tongue and/or throat (angioedema), which may cause difficulty in swallowing or breathing
- a rash or itching
- fainting
- yellowing of the skin and whites of the eyes, also called jaundice.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to DYNAVAL CO. You may need urgent medical attention. All of these are

very serious side-effects, but are less frequently experienced.

Side-effects that may occur frequently include:

- coughing
- muscle spasms.

If any of these persist or are bothersome, please consult your doctor, pharmacist or other healthcare professional immediately.

Less frequent side-effects that may occur include the following:

- viral infections, sore throat, sinusitis, blocked or runny nose
- loss of appetite (anorexia)
- fainting, dizziness, headache, restlessness, fever
- feeling dizzy when standing still
- blurred vision or seeing objects more yellow than they are
- diarrhoea, nausea, stomach pain or irritation, constipation
- liver problems, gout
- rash, hives, itchy skin, red patches on the skin, hair loss, sensitivity to light
- Stevens-Johnson syndrome (severe blistering, peeling and open sores on the skin)
- muscle cramps, back pain, joint pain
- kidney problems
- general tiredness or weakness.

If any of these persist or are bothersome, please consult your doctor, pharmacist or other healthcare professional as soon as possible.

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

6. STORING AND DISPOSING OF DYNAVAL CO

- ♦ Store at or below 25 °C.
- ♦ Keep the blisters in the carton until required for use.
- ♦ KEEP OUT OF THE REACH OF CHILDREN.
- ♦ Do not use the tablets after the expiry date shown on the carton or blister.
- ♦ Return the expired medicine to your pharmacist for safe disposal.
- ♦ Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF DYNAVAL CO

DYNAVAL CO film coated tablets are available in clear PVC/PE/PVDC / aluminium blister strips.

Pack sizes of 14, 28, 30, 56, 98 or 280 tablets in blister strips of 7, 10 or 15's are packed in an outer carton.

8. IDENTIFICATION OF DYNAVAL CO

DYNAVAL CO 80/12,5: Cylindrical, biconvex, coated and pink film coated tablets.

DYNAVAL CO 160/12,5: Cylindrical, biconvex, coated and reddish film coated tablets.

DYNAVAL CO 160/25: Cylindrical, biconvex, coated and brown film coated tablets.

9. REGISTRATION NUMBER

DYNAVAL CO 80/12,5: 44/7.1.3/0018

DYNAVAL CO 160/12,5: 44/7.1.3/0019

DYNAVAL CO 160/25: 44/7.1.3/0020

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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