

PROPOSED FINAL PATIENT INFORMATION LEAFLET for
DYNAVAL 80 AND 160 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DYNAVAL 80 mg film coated tablets

DYNAVAL 160 mg film coated tablets

Read all of this leaflet carefully before you start taking

DYNAVAL:

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

Active substance: Each film coated tablet contains 80 mg and 160 mg valsartan respectively.

Inactive ingredients: Colloidal silica anhydrous, Crospovidone, Magnesium stearate, Microcrystalline cellulose, Opadry Pink (80 mg) and Opadry Yellow (160 mg) (containing hypromellose, iron oxide red (pink), iron oxide yellow (yellow), macrogol and titanium dioxide).

DYNAVAL is sugar-free.

2. WHAT DYNAVAL IS USED FOR

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DYNAVAL is used in the treatment of:

- High blood pressure (hypertension).
- To treat patients after a recent heart attack.
- To treat symptomatic heart failure.

3. BEFORE YOU USE DYNAVAL

Do not take DYNAVAL if:

- You are hypersensitive (allergic) to any of the other ingredients in this medicine (see “**WHAT DYNAVAL CONTAINS**”).
- You are or think you may be pregnant, or if you are planning to become pregnant or if you are breastfeeding.
- You have a kidney disorder.
- You suffer from a narrowing of the kidney artery.
- You have recently undergone a kidney transplant (received a new kidney) or removal.
- 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**, again.
- You suffer from heart disease, including a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM).
- You are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride. **DYNAVAL** increases the amount of potassium in your blood.
- You suffer from porphyria (a rare blood disorder).
- You have a severe liver disease.
- You are currently taking lithium (used to treat depression and mood disorders). **DYNAVAL** increases the amount of lithium in your blood.

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- you are currently taking aliskiren-containing products (used to treat high blood pressure)

If any of the above apply to you, inform your doctor or pharmacist first and ask for their advice.

Take special care with DYNAVAL if:

There are certain conditions, which you may have, or have had, which require special care before or while using **DYNAVAL**. Before taking this medicine, you should tell your doctor if you suffer from the following:

- excessive vomiting
- diarrhoea
- kidney problems because the side effects of **DYNAVAL** may be increased.
- mild liver problems (see **DYNAVAL**).
- heart problems, your doctor should monitor your kidney function.
- low blood pressure
- you are already taking other medicines to treat heart failure such as ACE-inhibitors or aliskiren-containing medicines used to treat high blood pressure.
- you are on a low-salt diet
- you are taking high doses of water tablets (diuretics)

The first dose of **DYNAVAL** 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**. Your doctor should check the electrolyte content of your blood thereafter.

Taking DYNAVAL with food or drink:

The tablets can be taken with or without food.

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Pregnancy and Breastfeeding

DO NOT take **DYNAVAL** if you are pregnant or planning to become pregnant.

DO NOT take **DYNAVAL** during breastfeeding (see **Do not take DYNAVAL if**).

Driving and using machinery:

DYNAVAL may make you drowsy. Make sure you know how **DYNAVAL** affects you before driving or using machinery.

Important information about some of the ingredients of DYNAVAL:

DYNAVAL is sugar free.

Taking DYNAVAL with other medicines:

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

- You may experience dizziness, light-headedness or fainting when taking **DYNAVAL** with diuretics (water tablets), (see **Do not take DYNAVAL if**).
- Using **DYNAVAL** in combination with potassium-sparing diuretics, potassium supplements or salt substitutes containing potassium may lead to increased potassium concentration in the blood.
- Lithium (see **Do not take DYNAVAL if**).
- Non-steroidal anti-inflammatory medicines (NSAIDs) including aspirin (used for inflammation and pain).
- Medicines such as aliskiren, ACE inhibitors and beta blockers used to lower high blood pressure.

4. HOW TO TAKE DYNAVAL

Do not share medicines prescribed for you with any other person.

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Always take **DYNAVAL** as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will determine your dose according to your condition

The tablets should be taken at about the same time each day.

Do not stop treatment early, even if you feel better.

If you have the impression that the effect of **DYNAVAL** is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNAVAL than you should:

You may experience severe dizziness or fainting if you accidentally take too many **DYNAVAL** tablets.

In the event of overdose, consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take a dose of DYNAVAL:

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

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking **DYNAVAL** and contact your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat (angioedema) which may cause

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difficulty in swallowing or breathing

- a rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DYNAVAL**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty at your nearest hospital if you notice any of the following:

- Loss of water or body fluids (dehydration).
- Feeling sick, tired, muscle weakness or tingling sensations, irregular heartbeat or shortness of breath (hyperkalaemia).
- Viral infections.
- Fever, sore throat or mouth ulcers due to infections (symptoms of low levels of white blood cells also called neutropenia)
- Low blood pressure with or without symptoms, such as dizziness and fainting when standing up.
- Dizziness, light-headedness, fainting (especially when getting up from a lying or sitting position).
- Kidney problems (lower back or side pain, decreased frequency or amount of urine or bloody urine).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Headache, fainting.
- Feeling of fainting when standing up (vertigo).
- Coughing, upper respiratory tract infection, fever, sneezing, sore throat, sinusitis, blocked or runny nose.
- Unusual bleeding or bruising
- Swollen lymph nodes and/or flu-like symptoms (signs of serum sickness).
- Decreased levels of sodium in the blood, which can cause confusion, seizures, fatigue and low

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levels of consciousness (hyponatraemia).

- Diarrhoea, heartburn, stomach discomfort or pain, nausea
- Problems sleeping
- Problems with sexual performance
- Heart failure (signs include breathlessness, extreme tiredness, swelling in the ankles, feet, legs, abdomen and veins in the neck).
- Purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis).
- Decrease of red blood cells in the blood (which can lead to anaemia in severe cases).
- Elevation of liver function values (which can indicate liver damage).
- Kidney problems

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORAGE AND DISPOSAL OF DYNAVAL

- Store at or below 30 °C.
- Do not remove from outer carton until required for use.
- Protect from light and moisture.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

8. IDENTIFICATION OF DYNAVAL

DYNAVAL 80 mg: Pink coloured, round, biconvex tablets debossed with “80” on one side and score line on the other side.

DYNAVAL 160 mg: Yellow coloured, capsule shaped, biconvex, film coated tablet with “160” debossed on one side and score line on the other side.

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A handwritten signature in black ink, appearing to read "M. Wang", is located in the bottom right corner of the page.