PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

DYNARB 75 mg tablets

DYNARB 150 mg tablets

DYNARB 300 mg tablets

Read all of this leaflet carefully before you start taking DYNARB.

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

The active substance is irbesartan.

DYNARB 75 mg: Each tablet contains 75 mg irbesartan.

DYNARB 150 mg: Each tablet contains 150 mg irbesartan.

DYNARB 300 mg: Each tablet contains 300 mg irbesartan.

The other ingredients are:

Colloidal anhydrous silica, hydrogenated castor oil, magnesium stearate, maize starch, microcrystalline cellulose, povidone, sodium croscarmellose.

DYNARB 75 mg: Contains sugar (lactose monohydrate 15,4 mg)

DYNARB 150 mg: Contains sugar (lactose monohydrate 30,8 mg).

DYNARB 300 mg: Contains sugar (lactose monohydrate 61,5 mg).

2. WHAT DYNARB IS USED FOR:

DYNARB belongs to a group of medicines called angiotensin-II receptor antagonists.

DYNARB is used:

- To treat hypertension (high blood pressure)
- To protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

3. BEFORE YOU TAKE DYNARB:

Do not take DYNARB:

- If you are hypersensitive (allergic) to irbesartan or any of the other ingredients of **DYNARB** (see **WHAT DYNARB CONTAINS**)
- If you take lithium for mood disorders. This may lead to toxic blood concentrations of lithium
- If you have a history of angioedema (swellings similar to hives beneath the surface of the skin) related to previous therapy with **DYNARB** or other medicines containing the same active ingredient as **DYNARB** or with certain medicines used to treat heart conditions, called ACE inhibitors (angiotensin-converting enzyme inhibitors) or ARBs (angiotensin receptor blockers). If this is the case you may never use these medicines again
- If you suffer from hypertrophic obstructive cardiomyopathy (HOCM) (thickening of the muscle of the heart)
- If you have severe kidney disease, narrowing of the blood vessels of both kidneys, or you have only one kidney left, of which the blood vessels are narrowed
- If you have a disease of the heart valves called aortic stenosis in which the opening is narrowed
- contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin
- If you are also being treated with medicines called potassium sparing diuretics (e.g. spironolactone, triamterene or amiloride) that increase the rate of urination
- If you suffer from severe liver problems
- If you are, or think you may be, pregnant or if you are planning to become pregnant or if you

are breastfeeding.

DYNARB should not be given to children under the age of 6 years.

Take special care with DYNARB:

If you become pregnant while taking **DYNARB**, you should stop taking **DYNARB** immediately and inform your doctor. Your doctor should switch you to a different medicine.

Tell your doctor:

- If you are being treated with a diuretic (water tablet) or are on a salt restricted diet as you may experience a serious drop in blood pressure (hypotension)
- If you suffer from excessive vomiting or diarrhoea
- If you have kidney problems
- If you suffer from diabetes
- If you experience fatigue or muscle weakness as these may be symptoms of a condition called hyperkalaemia
- If you suffer from a hormonal disorder called primary aldosteronism
- If you are a black patient as **DYNARB** may not effectively lower your blood pressure.

Your doctor may request tests to monitor your condition before or during treatment.

Taking DYNARB with food and drink:

DYNARB can be taken with or without food.

Pregnancy and breastfeeding:

DYNARB should not be used if you are pregnant or breastfeeding (see **Do not take DYNARB**).

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **DYNARB**.

Driving and using machinery:

DYNARB can cause dizziness. Do not drive or operate machines until you know how **DYNARB**

affects you.

Important information about some of the ingredients of DYNARB:

DYNARB contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **DYNARB**. **DYNARB** contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with DYNARB:

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

(This includes complementary or traditional medicines).

Medicines that may interact with **DYNARB**:

- contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin
- Other medicines from the same class (angiotensin II receptor antagonists or ACE inhibitors) to lower blood pressure, including those that contain aliskiren
- Potassium-sparing diuretics (water tablets)
- Potassium supplements or salt substitutes containing potassium (these may lead to increased potassium concentrations in the blood)
- Medicines containing lithium (used for depression)
- Certain medicines used to treat pain and inflammation called NSAIDs (non-steroidal anti-inflammatory medicines) as the effect of **DYNARB** may be reduced.

4. HOW TO TAKE DYNARB:

Do not share medicines prescribed for you with any other person. Always take **DYNARB** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults:

The usual dose is 150 mg once daily, with or without food. The dose of **DYNARB** can be increased to 300 mg once daily, depending on your blood pressure response.

Your doctor will decide on the dose depending on your condition.

For children and adolescents: your doctor will decide on the correct dosage depending on the age.

Your doctor will tell you how long your treatment with **DYNARB** will last.

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

If you take more DYNARB than you should

In the event of an overdose, contact your doctor or pharmacist. If neither is available, contact 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.

The following side effects may occur in overdose: fever, faintness, flushing, hypotension (low blood pressure), drowsiness, agitation and seizures.

If you forget to take a dose of DYNARB:

If you forget to take a **DYNARB** tablet, take one as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with DYNARB is stopped:

It is important that you **continue the course of treatment** even if you begin to feel better after a few days.

5. POSSIBLE SIDE EFFECTS:

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

Should your general health worsen, or if you experience any untoward effects while taking **DYNARB**

please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking **DYNARB** 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 swallowing or breathing
- rash or itching
- jaundice (yellowing of the skin and eyes).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DYNARB**. 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:

- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever)
- increased or fast heart beat (tachycardia)
- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- hepatitis (inflammation of the liver with symptoms such as loss of appetite and fatigue)
- Henoch-Schonlein purpura (inflammation of small blood vessels, with symptoms such as rash or many small bruises)
- rhabdomyolysis (a condition affecting the muscles with symptoms such as dark urine and difficulty moving arms or legs)
- kidney problems (passing less urine than is normal for you)
- teratogenic effects (giving birth to a baby with birth defects)
- chest pain (angina)
- hyperkalaemia (a condition that causes fatigue, weakness, feeling of numbness, chest pain and palpitations or skipped heart beats)
- a decrease of blood sugar in patients suffering from diabetes (high blood sugar).

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

Tell your doctor if you notice any of the following:

- increased risk of infections (signs of infection include fever/chills or a sore throat)
- dizziness, light-headedness, headache, constant headache that affects one side of the head (migraine)
- ringing sound in the ear (tinnitus)
- low blood pressure or fainting when getting up from a lying or sitting position (orthostatic hypotension/dizziness), face becoming red and hot
- cough and common cold
- feeling sick, vomiting, diarrhoea, stomach discomfort, heartburn, taste disturbances
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)
- skin disorders
- muscle weakness, muscle cramps, pain in muscle, pain in joints
- problems with sexual performance
- unusual tiredness, chest pain.

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

6. STORING AND DISPOSING OF DYNARB:

Store at or below 25 °C.

Keep the blister in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

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