

**PROPOSED PATIENT INFORMATION LEAFLET FOR  
DYNARB 75 mg / 150 mg / 300 mg**

<p><b>Please read this leaflet carefully before using DYNARB tablets</b></p> <ul style="list-style-type: none"><li>• Keep this leaflet. You may need to read it again.</li><li>• If you have any further questions, please ask your doctor or your pharmacist.</li><li>• <b>DYNARB</b> 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.</li></ul> <p><b>SCHEDULING STATUS</b></p> <p>S3</p> <p><b>PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM</b></p> <p><b>DYNARB 75 mg</b> (tablets) <b>DYNARB 150 mg</b> (tablets) <b>DYNARB 300 mg</b> (tablets)</p> <p><b>1. WHAT DYNARB CONTAINS</b></p> <p><b>DYNARB 75 mg:</b> Each tablet contains 75 mg irbesartan. <b>DYNARB 150 mg:</b> Each tablet contains 150 mg irbesartan. <b>DYNARB 300 mg:</b> Each tablet contains 300 mg irbesartan.</p> <p><b>DYNARB</b> also contains lactose monohydrate.</p> <p><b>Inactive ingredients:</b> Povidone, magnesium stearate, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, hydrogenated castor oil and maize starch.</p> <p><b>DYNARB</b> contains the sugar, lactose monohydrate as an inactive ingredient.</p>	
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Therefore, if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **DYNARB** (see “**Take special care with DYNARB**”).

## 2. WHAT DYNARB IS USED FOR

**DYNARB** is used in the treatment of high blood pressure (hypertension) and for the protection of the kidney in hypertensive type 2 diabetic patients.

## 3. BEFORE YOU USE DYNARB

**Do not take DYNARB if you:**

- Are allergic (hypersensitive) to any of the ingredients in this medicine (see “**WHAT DYNARB CONTAINS**”).
- 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.
- Have a family history of angioedema (swellings similar to hives beneath the surface of the skin) or angioedema from no known cause.
- Suffer from hypertrophic obstructive cardiomyopathy (thickening of the muscle of the heart).
- 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.
- Have a disease of the heart valves in which the opening is narrowed.
- Are concomitantly treated with medicines called potassium sparing diuretics

(e.g. spironolactone, triamterene or amiloride) that elevates the rate of urination.

- Have been told by your doctor that you suffer from porphyria (an inherited or acquired disorder of certain enzymes in the liver).
- Are receiving lithium therapy (a mood stabilizer); concomitant administration with **DYNARB** may lead to toxic blood concentrations of lithium.
- 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.

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

**Take special care with DYNARB:**

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

- excessive vomiting
- diarrhoea
- kidney problems
- heart problems
- an intolerance to some sugars (e.g.lactose)

When you receive **DYNARB** for diabetic renal disease, your doctor may perform regular blood tests, especially to measure blood potassium levels in case of poor kidney function.



<p><b>Taking DYNARB with food or drink:</b></p> <p><b>DYNARB</b> can be taken with or without food.</p> <p><b>Pregnancy and breastfeeding:</b></p> <p>DO NOT use <b>DYNARB</b> if you are pregnant or suspect that you are pregnant. Contact your doctor or healthcare professional immediately.</p> <p>DO NOT use <b>DYNARB</b> during breastfeeding.</p> <p><b>DYNARB</b> may cause harm to your unborn baby.</p> <p><b>Driving and using machinery:</b></p> <p><b>DYNARB</b> may not affect your ability to drive or use machines. However, occasionally, dizziness or weariness may occur during treatment of high blood pressure. If you experience these symptoms, you should consult your doctor before attempting such activities. However, please make sure you know how <b>DYNARB</b> affects you before driving or using machinery.</p> <p><b>Using other medicines with DYNARB:</b></p> <ul style="list-style-type: none"><li>• Consult with your doctor or pharmacist or healthcare professional for advice if you need to take any other medicines.</li><li>• If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of <b>DYNARB</b> with these medicines may cause undesirable interactions.</li></ul> <p>Consult your doctor or pharmacist before taking such medicines.</p> <ul style="list-style-type: none"><li>• You may experience dizziness, light-headedness or fainting when taking <b>DYNARB</b> with diuretics. Please consult your doctor if this happens.</li><li>• Medicines such as tolbutamide may interact with <b>DYNARB</b>.</li></ul>	
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- Using **DYNARB** in combination with potassium-sparing diuretics, potassium supplements or salt substitutes containing potassium may lead to increased potassium concentration in the blood.

If you are due to have an operation, tell the anaesthetist or the medical staff you are taking **DYNARB**.

#### **4. PROPER USE OF DYNARB**

The dose of **DYNARB** will be different for each patient and may depend on what the medicine is being used for, your age and if other medicines are also being given or taken at the same time.

Your doctor will advise you what the best dosage for you will be. In most patients 75 to 150 mg per day will be adequate. The maximum recommended dose is 300 mg per day. The tablets should be taken at about the same time each day.

If you have any questions about the proper dose of **DYNARB**, ask your doctor or pharmacist.

#### **If you take more DYNARB than you should:**

In the event of overdosage, 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.

#### **5. POSSIBLE SIDE-EFFECTS**

**DYNARB** may have side-effects.

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

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



<p>If any of the following happen, stop taking <b>DYNARB</b> and contact your doctor or healthcare professional immediately:</p> <ul style="list-style-type: none"><li>• swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing</li><li>• a rash or itching</li></ul> <p>These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to <b>DYNARB</b>. You may need urgent medical attention. All of these side-effects are very serious, but are very rare.</p> <p>Some side-effects may occur that usually do not need medical attention.</p> <ul style="list-style-type: none"><li>• Dizziness, light-headedness, fainting (especially when getting up from a lying or sitting position).</li><li>• Confusion, irregular heartbeat, numbness or tingling in hands, feet or lips, difficult breathing, or weakness, or heaviness of the legs.</li><li>• Nausea, vomiting.</li><li>• Unusual tiredness.</li><li>• Headache.</li><li>• Fast heartbeat.</li><li>• Coughing.</li><li>• Diarrhoea, heartburn, stomach discomfort.</li><li>• Problems with sexual performance.</li><li>• Chest pain.</li><li>• Clay-coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin.</li></ul> <p><b>6. STORAGE AND DISPOSAL OF DYNARB</b></p> <ul style="list-style-type: none"><li>• Store at or below 25 °C.</li><li>• Do not remove from outer carton until required for use.</li></ul>	
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<p>• <b>KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.</b></p> <ul style="list-style-type: none"><li>• Return all unused medicine to your pharmacist.</li><li>• Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).</li></ul> <p><b>7. PRESENTATION OF DYNARB</b></p> <p><b>DYNARB 75 mg, 150 mg and 300 mg</b> tablets are packed into white PVC /PVDC / aluminium foil blisters. 10 or 15 tablets are placed into a blister strip.</p> <p>3 x 10 or 2 x 15 tablets with a package insert is placed in a cardboard carton.</p> <p><b>8. IDENTIFICATION OF DYNARB</b></p> <p><b>DYNARB 75 mg:</b></p> <p>White, cylindrical, biconvex tablets <del>with a diameter of 8 mm.</del></p> <p><b>DYNARB 150 mg:</b></p> <p>White, cylindrical, biconvex, scored tablets <del>with a diameter of 11 mm.</del></p> <p><b>DYNARB 300 mg:</b></p> <p>White, oblong, biconvex, scored tablets <del>with dimensions 18,3 mm x 8,2 mm.</del></p> <p><b>9. REGISTRATION NUMBERS</b></p> <p><b>DYNARB 75 TABLETS:</b> <u>RSA S3 43/7.1.3/0719 NAM NS2 12/7.1.3/0222</u></p> <p><b>DYNARB 150 TABLETS:</b> <u>RSA S3 43/7.1.3/0720 NAM NS2 12/7.1.3/0223</u></p> <p><b>DYNARB 300 TABLETS:</b> <u>RSA S3 43/7.1.3/0721 NAM NS2 12/7.1.3/0224</u></p> <p><b>10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION</b></p>	<p>Changes made in line with the type a, category 10 amendment to remove the dimensions from the tablet descriptions</p> <p>Addition of the SA and Namibian registration details in line with registration approvals received.</p>
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