PATIENT INFORMATION LEAFLET

DYNARB RANGE

SCHEDULING STATUS

S3

DYNARB 150 mg tablets

DYNARB 300 mg tablets

Irbesartan

DYNARB contains sugar (lactose monohydrate): Each 150 mg tablet contains 30,8 mg and each 300 mg tablet contains 61,5 mg of lactose monohydrate).

DYNARB is 'essentially sodium free'.

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, pharmacist, nurse or other healthcare provider.
- 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.

What is in this leaflet

1. What DYNARB is and what it is used for
2. What you need to know before you take DYNARB
3. How to take DYNARB
4. Possible side effects
5. How to store DYNARB
6. Contents of the pack and other information

1. What DYNARB is and what it is used for

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

DYNARB is used:

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

2. What you need to know before you take DYNARB

Do not take DYNARB:

- if you are hypersensitive (allergic) to irbesartan, or to any of the ingredients of DYNARB (see section 6)
- 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 have hereditary angioedema (swelling around your face, throat or tongue)
- 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.
- 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 have kidney problems and are taking fluoroquinolones (used to treat bacterial infections) at the same time (see Other medicines with DYNARB)
- if you have a disease of the heart valves called aortic stenosis in which the opening is narrowed

- 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
- if you have porphyria (a rare hereditary blood disease)
- if you are taking a medicine called aliskiren to treat high blood pressure.

DYNARB should not be given to children.

Warnings and precautions

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 have heart 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 have kidney disease or are an elderly patient and are taking fluoroquinolones (used to treat bacterial infections)
- if you are taking medicine containing lithium.

- if you receive DYNARB for diabetic kidney disease. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function
- if you suffer from a hormonal disorder called primary aldosteronism
- if you suffer from heart problems
- if you develop low blood sugar levels (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat), particularly if you are being treated for diabetes
- 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.

DYNARB should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

Other medicines and 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 (nonsteroidal anti-inflammatory medicines) as the effect of DYNARB may be reduced
- repaglinide (medication used for lowering blood sugar levels).

DYNARB with food and drink

DYNARB can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using DYNARB.

DYNARB should not be used if you are pregnant or breastfeeding (see Do not take DYNARB).
You should ensure adequate contraception while taking DYNARB if you are of childbearing age.

Driving and using machines

DYNARB can cause dizziness or fatigue. Do not drive or operate machines until you know how DYNARB affects you.
It is not always possible to predict to what extent DYNARB may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DYNARB affects them.

DYNARB contains lactose

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

DYNARB contains less than 1 mmol sodium (0,023 mg) per dose, that is to say essentially ‘sodium

free'.

3. How to take DYNARB

Do not share medicines prescribed for you with any other person. Always use DYNARB exactly as your doctor has instructed. 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.

Children:

DYNARB should not be given to children under 18 years of age.

Your doctor will tell you how long your treatment with DYNARB will last. Do not stop treatment early because your high blood pressure may return.

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 overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- fever, faintness, flushing, hypotension (low blood pressure), drowsiness, agitation and seizures.

If you forget to take DYNARB

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

If you stop taking DYNARB

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

4. 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 using DYNARB, please consult your healthcare provider for advice.

If any of the following happens, stop using DYNARB and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, 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:

Frequent side effects:

- dizziness, light-headedness, headache
- sudden internal or external spinning sensation (vertigo)
- low blood pressure or fainting when getting up from a lying or sitting position (orthostatic hypotension/dizziness)
- nausea, vomiting
- pain in muscle, pain in joints
- unusual tiredness
- abnormal blood test results in diabetic patients with advanced kidney disease.

Less frequent side effects:

- increased risk of infections (signs of infection include fever/chills or a sore throat)
- face becoming red and hot
- cough and common cold, chest infection
- diarrhoea, stomach discomfort, heartburn, taste disturbances
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)
- skin disorders
- problems with sexual performance
- chest pain, back pain.

The following side effects have been reported but the frequency for them to occur is not known:

- blood disorders including anaemia and a deficiency of platelets in the blood, which causes bleeding into the tissues, bruising, and slow blood clotting after injury
- migraine
- ringing sound in the ear (tinnitus)
- muscle weakness, muscle cramps, abnormal physical weakness or lack of energy
- swelling caused by excess fluid trapped in your body's tissues.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following links: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of DYNARB. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store DYNARB

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep blisters in carton until required for use.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DYNARB contains:

DYNARB 150 mg: The active ingredient in each tablet is 150 mg irbesartan.

DYNARB 300 mg: The active ingredient in each tablet is 300 mg irbesartan.

The other ingredients are:

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

What DYNARB looks like and contents of the pack

DYNARB 150 mg: White, cylindrical, biconvex, scored on one side, tablets with a diameter of 11 mm.

DYNARB 300 mg: White, oblong, biconvex, scored on one side, tablets with dimensions of 18,3 mm x 8,2 mm.

White opaque PVC/PVDC/ aluminium foil blisters. DYNARB is available in pack sizes of 30 tablets

placed in a printed carton, with a package insert.

Holder of Certificate of Registration

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MOZAMBIQUE

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DYNARB 300 mg: C7122