

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

SCHEDULING STATUS:

S3

Dyna Indapamide SR, sustained release tablets

Indapamide 1,5 mg

DYNA INDAPAMIDE SR contains sugar (lactose monohydrate 91,125 mg per tablet)

Read all of this leaflet carefully before you start taking DYNA INDAPAMIDE SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DYNA INDAPAMIDE SR 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 DYNA INDAPAMIDE SR is and what it is used for
2. What you need to know before you use DYNA INDAPAMIDE SR
3. How to use DYNA INDAPAMIDE SR
4. Possible side effects
5. How to store DYNA INDAPAMIDE SR, contents of the pack and other information
6. Contents of the pack and other information

1. What DYNA INDAPAMIDE SR is and what it is used for

DYNA INDAPAMIDE SR contains Indapamide, one of a group of medicines called vasodilators.

DYNA INDAPAMIDE SR is prescribed by doctors to treat high blood pressure.

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

2. What you need to know before you take DYNA INDAPAMIDE SR

Do not take DYNA INDAPAMIDE SR:

- if you are allergic (hypersensitive) to indapamide, other sulphonamide type medications (also called sulfa medications and used for the treatment of different infections), or any of the components of DYNA INDAPAMIDE SR.

Please inform your doctor if you are allergic to sulphonamide type medicines (sulfa medications), especially if you have had incidents of allergic reactions after receiving such medicines.

- if you are pregnant or while you are breastfeeding, as the safety of DYNA INDAPAMIDE SR in pregnancy and breast feeding is not known.
- severe liver disease
- severe kidney disease

Warnings and precautions

Special care should be taken with DYNA INDAPAMIDE SR:

- if you are elderly as you may be more sensitive to the electrolyte and blood pressure lowering effect of DYNA INDAPAMIDE SR
- if you have kidney damage or are unable to urinate
- if you have diabetes, monitoring of blood glucose (blood sugar) is important in the presence of hypokalaemia.
- if you suffer from gout, which may worsen due to increased levels of uric acid in the blood
- if you have any damage to your liver resulting in loss of liver function
- if you had a sympathectomy (operation to block a nerve in the middle of your body to treat conditions such as excessive sweating or severe facial flushing/blushing)

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

- if you are allergic to other sulphonamide-type medicines that may lead to allergic reaction when taking DYNA INDAPAMIDE SR
- if you have electrolyte imbalance due to dehydration. Your doctor may check for low sodium or potassium levels or high calcium levels
- if you have an irregular heart rhythm condition
- if you are taking other diuretics while taking DYNA INDAPAMIDE SR it may cause hypokalaemia, and is not recommended
- if your liver does not function properly, DYNA INDAPAMIDE SR should not be taken
- if you have a photosensitivity reaction while taking DYNA INDAPAMIDE SR. If you have to continue taking the medication, it is recommended to protect exposed areas to the sun or to artificial UVA.
- if you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you should not take this medicine.
- if you are an athlete, you must be aware of the fact that this medicinal product contains a drug substance, which may give a positive reaction in doping tests.

Children and adolescents:

Children: Safety and efficacy has not been established and DYNA INDAPAMIDE SR is not recommended for use in children.

Other medicines and DYNA INDAPAMIDE SR

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

- lithium (used to treat depression) due to increased levels of lithium in the blood

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

- The following medicines if used with DYNA INDAPAMIDE SR can cause serious abnormal heart rhythm
- medications used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide)
- medications used to treat mental disorders such as depression, anxiety, schizophrenia, some antipsychotics: phenothiazines (chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine), benzamides (amisulpride, sulpiride, sultopride, tiapride) butyrophenones (droperidol, haloperidol)
- other medicines - bepridil (to treat angina), cisapride (to treat gastric reflux), diphemanil (treat excessive sweating), antibiotics -erythromycin IV, sparfloxacin and moxifloxacin, halofantrine (to treat malaria), mizolastine (anti-allergy medicine), pentamidine (to treat pneumonia), vincamine IV (to treat high blood pressure)
- non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of aspirin may decrease effect of DYNA INDAPAMIDE SR
- angiotensin converting enzyme (ACE) inhibitors, e.g. enalapril, ramipril (used to treat high blood pressure and heart failure) may increase effect of DYNA INDAPAMIDE SR
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis) may increase effect of DYNA INDAPAMIDE SR
- allopurinol (for the treatment of gout) as hypersensitivity/allergic reactions may be increased
- digoxin (to treat angina) – toxic effects may be increased
- metformin (used in the treatment of diabetes) results in an increased risk of lactic acidosis (too much lactic acid in the body) with symptoms such as stomach discomfort, muscle pain, muscle cramping, unusual tiredness or weakness
- iodinated contrast media (used for tests involving X-rays) increase the risk of kidney

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

disease

- imipramine (to treat depression) may increase risk of low blood pressure when getting up from a lying or sitting position
- calcium tablets or other calcium supplements may increase calcium levels in the blood
- angiotensin converting enzyme (ACE) inhibitors, e.g. enalapril, ramipril (used to treat high blood pressure and heart failure) may increase effect of DYNA INDAPAMIDE SR
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis) may increase effect of DYNA INDAPAMIDE SR
- ciclosporin, tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases
- corticosteroids, tetracosactide, decreases the effect of DYNA INDAPAMIDE SR.

DYNA INDAPAMIDE SR with food and drink and alcohol

DYNA INDAPAMIDE SR can be taken with or without food.

Pregnancy, breastfeeding and fertility

DO NOT use DYNA INDAPAMIDE SR if you are pregnant or suspect that you are pregnant

Contact your doctor immediately.

DO NOT use DYNA INDAPAMIDE SR if you are breast feeding.

DYNA INDAPAMIDE SR contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

3. How to take DYNA INDAPAMIDE SR

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

Always use DYNA INDAPAMIDE SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults:

Take one DYNA INDAPAMIDE SR tablet every day, preferably taken on arising in the morning.

Always take DYNA INDAPAMIDE SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The tablet should be swallowed whole with water and not chewed preferably taken when waking in the morning

Your doctor will tell you how long your treatment with DYNA INDAPAMIDE SR will last.

If you have the impression that the effect of DYNA INDAPAMIDE SR is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNA INDAPAMIDE SR than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- allergic skin rashes
- stomach pain
- nausea
- photosensitivity (extreme sensitivity to ultraviolet (UV) rays from the sun and other

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

sources of light)

- dizziness
- weakness and tingling or pricking feeling on the skin ('pins and needles').

If you forget to take DYNA INDAPAMIDE SR:

If you forget to take DYNA INDAPAMIDE SR, take the next dose as soon as you remember, then continue to take DYNA INDAPAMIDE SR at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DYNA INDAPAMIDE SR

The treatment for high blood pressure is usually life-long and you should discuss with your doctor before stopping this medicinal product.

4. Possible side effects

DYNA INDAPAMIDE SR can have side effects.

Not all side effects reported for DYNA INDAPAMIDE SR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNA INDAPAMIDE SR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking DYNA INDAPAMIDE SR 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

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

- fainting

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

- difficulty breathing, shortness of breath, tight chest
- fainting
- abnormal heart rhythm which can lead to sudden cardiac death
- reduced liver function with symptoms such as include abdominal pain or swelling, jaundice, nausea and vomiting, diagnosed with hepatitis (viral infection of the liver) (viral infection of the liver, cholestatic jaundice (symptoms include yellow skin or eyes)
- toxic epidermic necrolysis and Stevens-Johnson syndrome (fever and flu-like symptoms followed by skin blisters and peeling)
- kidney failure, symptoms include loss of appetite and fatigue)

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:

- both flat and raised 'bumps' on the skin

Less frequent side effects:

- abnormal blood counts, anaemia, tendency to bleed easily
- electrolyte imbalance – sodium, potassium (symptoms such as tiredness and leg cramps), calcium

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

- headaches, dizziness especially when standing up from lying or sitting position), tiredness, 'pins and needles' feeling on the skin
- low blood pressure
- anorexia (eating disorder characterized by low body weight), stomach pain, gas and bloatedness, nausea, vomiting, constipation, diarrhoea, dry mouth, pancreatitis (inflammation of the pancreas)
- discolouration of the skin produced by small bleeding vessels, urticaria or hives (a kind of skin rash with red, raised, itchy bumps).

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

- short sightedness, blurred vision, vision loss
- possible worsening of pre-existing acute disseminated lupus erythematosus (collection of autoimmune diseases in which the immune system attacks healthy tissues), photosensitivity reactions (an extreme sensitivity to ultraviolet (UV) rays from the sun and other sources of light)
- abnormal electrocardiogram (showing the heartbeat pattern), blood tests showing increased glucose/sugar levels, uric acid and liver enzyme levels.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR

By reporting side effects, you can help provide more information on the safety of DYNA INDAPAMIDE SR.

5. How to store DYNA INDAPAMIDE

Store all medicines out of reach of children

Store at or below 25 °C in original container

Do not remove the blisters from the outer 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 DYNA INDAPAMIDE SR contains

The active substance is Indapamide.

Each tablet contains 1.5 mg Indapamide

The other ingredients are:

Hypromellose, cellactose (a combination of alpha-lactose monohydrate and cellulose powder), povidone, silica (colloidal anhydrous), magnesium stearate, opadry Y-1-7000 (a combination of titanium dioxide, hypromellose and macrogol 400).

What DYNA INDAPAMIDE SR looks like and contents of the pack

DYNA INDAPAMIDE SR film coated tablets are white, round, slightly biconvex film tablets. It is packed in aluminium foil and transparent, hard PVC/PVDC foil blister strips of 3 x 10 tablets inside an outer carton box

**PATIENT INFORMATION LEAFLET
DYNA INDAPAMIDE SR**

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

09 July 2021

Registration number

A42/7.1/0790

NAM:

NS2 12/7.1/0138

Access to the corresponding Professional Information

For Healthcare Professional access to the Professional Information, please visit

<https://www.mydynamics.co.za/products-healthcare-professionals/>.