NEW ZEALAND CONSUMER MEDICINE INFORMATION



DAPA-TABS

Indapamide hemihydrate Tablet 2.5 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Dapa-Tabs.

This leaflet answers some common questions about Dapa-Tabs.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Dapa-Tabs against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DAPA-TABS is used for

Dapa-Tabs is used either alone or in combination with other medicines to treat high blood pressure (hypertension).

Dapa-Tabs contains the active ingredient indapamide hemihydrate, which is thought to work by relaxing some of the blood vessels in the body causing blood pressure to fall. The exact way in which it does this however, is not fully understood.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine in children.

There is no evidence that Dapa-Tabs is addictive.

Before you take DAPA-TABS

When you must not take it:

Do not take Dapa-Tabs if you have an allergy to:

- Any medicine containing indapamide hemihydrate
- Sulfonamide or sulfa (sulpha) medicines
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Dapa-Tabs if you have:

- Severe liver disease
- Severe kidney problems
- Low potassium levels in your blood.

Do not take this medicine if you are pregnant or plan to become pregnant.

There is limited information on the use of Dapa-Tabs in pregnancy, therefore, Dapa-Tabs is not recommended for use in pregnant women.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

Dapa-Tabs is not recommended for use in breastfeeding women, as this medicine passes into breast milk and the effect on your baby in unknown.

Do not give this medicine to a children. Safety and effectiveness in children have not been established. Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Systemic lupus erythematosus (SLE)
- Gout
- Diabetes
- Water and electrolyte imbalance
- Heart rhythm problems
- Low blood pressure
- Kidney problems
- Liver problems.

Your doctor may want to take special care if you have any of these conditions.

Athletes should be aware that indapamide may give a positive reaction in doping tests.

If you have not told your doctor about any of the above, tell him/her before you start taking Dapa-Tabs.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Dapa-Tabs may interfere with each other. These include:

- Lithium, a medicine used to treat mood swings and some types of depression
- Medicines to treat mental illnesses such as some medicines for epilepsy, anxiety (e.g. droperidol, haloperidol, chlorpromazine, trifluoperazine), schizophrenia (e.g. amisulpride, sulpride) and some other antidepressants (e.g. imipramine, citalopram, escitalopram)
- Donepezil, a medicine used to treat Alzheimer's disease
- Other medicines used to treat high blood pressure, a fast or irregular heartbeat (e.g. disopyramide, amiodarone) and other heart conditions (e.g. digoxin)
- Other diuretics, also known as water or fluid tablets (e.g. amiloride, spironolactone, triamterene).
- Non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of aspirin
- Corticosteroids, medicines used in the treatment of conditions such as allergic reactions, asthma, inflammatory and autoimmune diseases
- Strong pain killers
- Calcium supplements
- Stimulant laxatives
- Baclofen, a medicine used to treat muscle stiffness occurring in diseases such as multiple sclerosis
- Metformin, a medicine used to treat diabetes
- Ciclosporin, tacrolimus medicines used to treat certain immune system problems
- Medicines used to treat bacterial infections (e.g.

- moxifloxacin, ciprofloxacin, clarithromycin, erythromycin by IV.)
- Moxifloxacin, an antibiotic medicine used to treat infections
- Contrast media dyes used during some radiographic procedures
- Allopurinol, a medicine used to treat gout.
- Chloroquine, an antiparasitic medicine used to treat certain types of malaria.
- Pentamidine, a medicine used to treat certain types of pneumonia.
- Ondansetron and domperidone, medicines used to treat nausea and vomiting.
- Vandetanib and oxaliplatin, medicines used to treat cancer.
- Anagrelide, a medicine used to reduce elevated blood platelet counts.
- Methadone, a medicine used to treat addiction.
- Cilostazol, a medicine used to treat leg cramps.
- Tetracosactide (tetracosactrin), a medicine used to treat Crohn's disease.
- Disopyramide, amiodarone, sotalol and flecainide, medicines used to treat heart rhythm problems.
- Medicines used to treat fungal infections (e.g. amphotericin B IV, fluconazole)
- Papaverine, a medicine used to treat gastrointestinal problems.
- Anaesthetics (e.g. propofol, sevoflurane)

These medicines may be affected by Dapa-Tabs or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take DAPA-TABS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual adult dose is one tablet daily, taken in the morning.

How to take it

Swallow the tablets whole with a full glass of water.

Do not halve the tablets.

When to take it

Take your medicine at about the same time each morning.

Taking it at the same time each morning will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking DAPA-TABS

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Dapa-Tabs.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking] this medicine.

It may affect other medicines used during surgery. If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to check your blood pressure, kidney function, sodium levels and potassium levels from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Dapa-Tabs to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not let yourself run out of Dapa-Tabs over weekends or on holidays.

Things to be careful of

Be careful driving or operating machinery until you know how Dapa-Tabs affects you.

This medicine may cause tiredness,

dizziness and light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Dizziness or light-headedness may be worse if you drink alcohol, take strong pain killers, barbiturates or other medicines for high blood pressure while being treated with Dapa-Tabs.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Make sure you drink enough water in hot weather and during exercise when you are taking Dapa-Tabs, especially if you sweat a lot.

Also make sure you tell your doctor straight away if you become sick and have severe or continuing vomiting or diarrhoea while taking Dapa-Tabs as these may affect how Dapa-Tabs is processed by your body.

The loss of additional water and certain salts such as potassium from the body may make you feel faint, light-headed, weak or sick.

Dapa-Tabs may cause your skin to become sensitive to the sun. If this happens you should contact your doctor. Protect your skin from too much sunlight.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Dapa-Tabs. Do this even if there are no signs of

discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dapa-Tabs.

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Loss of appetite
- Feeling sick or stomach upset
- Tiredness or weakness
- Muscle weakness, pain or cramp
- Changes in blood sugar levels
- Bleeding or bruising more easily than normal
- Dizziness or lightheadedness, especially when getting up from a sitting or lying position
- Headache
- Diarrhoea, constipation
- Increased sensitivity of the skin to sunlight
- Fever, soreness of the throat or other flu-like symptoms
- Tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- Blurred vision, short sightedness or visual impairment.

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

- Signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.
- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Fast or irregular heart beat
- · Chest pain
- Signs of a water or salt, e.g. potassium, imbalance in the body. Symptoms may include:
 - Dryness of mouth
 - Increased thirst
 - o Irregular heartbeat
 - Weak pulse
 - o Muscle cramps or pain
 - Nausea or vomiting
 - Unusual tiredness or weakness
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. This is not a complete list of all possible side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking DAPA-TABS

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Dapa-Tabs or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Dapa-Tabs is a round, pink, film-coated tablet marked 'IE' over '2.5' on one side and 'G' on the other side.

Each blister pack contains 90 tablets.

Ingredients

Active Ingredient:

Dapa-Tabs tablet contains 2.5 mg of indapamide hemihydrate as the active ingredient.

Inactive Ingredients:

Dapa-Tabs also contains:

- Sodium starch glycollate
- Magnesium stearate
- Cellulose microcrystalline
- Lactose anhydrous
- Croscarmellose sodium
- Opadry Pink OY-6953.

Contains lactose and sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Dapa-Tabs is supplied d in New Zealand by:

Viatris Ltd, PO Box 11-183, Ellerslie, Auckland www.viatris.co.nz Telephone: 0800168 169

Date of Preparation

07 July 2022 (Based on datasheet dated 07 July 2022).