

DAPA-TABS®

indapamide hemihydrate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about DAPA-TABS.

It is not to be used in relation to any other product, which may also contain the same active ingredient.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking DAPA-TABS against the benefits expected for you.

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

Keep this leaflet with your 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 in the treatment of high blood pressure (hypertension).

DAPA-TABS contains the active ingredient indapamide hemihydrate, which belongs to a group of medicine called chlorosulphamoyl diuretics (a type of "fluid" or "water" tablet).

Why DAPA-TABS is used for high blood pressure

Everyone has blood pressure. This pressure helps to circulate blood all around the body. Your blood pressure may be different at different

times of the day, depending on how busy or stressed you are.

You have high blood pressure (also known as hypertension) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems.

You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

DAPA-TABS helps to lower blood pressure.

Ask your doctor if you have any questions about why DAPA-TABS has been prescribed for you.

Your doctor may have prescribed DAPA-TABS for another purpose.

DAPA-TABS is not recommended for use in children, as its safety and effectiveness in children have not been established.

DAPA-TABS is available only with a doctor's prescription.

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:

- medicines containing indapamide.
- sulfonamide or sulfa (sulpha) antibiotics, or thiazide diuretics (a type of "fluid" or "water" tablet).

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include 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.

Do not take DAPA-TABS if you have:

- severe liver disease or if you suffer from a condition called hepatic encephalopathy, a liver problem which affects the brain and central nervous system.
- severe kidney problems such as anuria or progressive and severe oliguria.
- low potassium levels in your blood.

Do not take DAPA-TABS if you are pregnant or plan to become pregnant.

There is no information on the use of DAPA-TABS in pregnancy.

Therefore, DAPA-TABS is not recommended for use in pregnant women. Medicines of this type have been associated with unwanted effects in the unborn baby.

Do not take DAPA-TABS if you are breastfeeding or plan to breastfeed.

DAPA-TABS is not recommended for use in breastfeeding women, as it is not known whether this medicine passes into breast milk and how it may affect your baby.

Do not take DAPA-TABS if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take DAPA-TABS if the packaging shows signs of tampering or the tablets do not look quite right.

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 are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have an intolerance to lactose.

Tell your doctor if you have any medical conditions, especially the following:

- high or low levels of potassium, sodium, or other problems with salt balance
- systemic lupus erythematosus (SLE), a disease affecting the skin, joints and kidneys
- gout
- diabetes
- you have previously experienced an increased sensitivity to sunlight (photosensitivity reactions)
- heart rhythm problems
- kidney problems
- liver problems.
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking DAPA-TABS. This can lead to permanent vision loss, if not treated. If you have a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- you have muscle disorders including muscle pain, tenderness, weakness or cramps.

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

Tell your doctor if have done or are planning to do a test to check

how well your parathyroid gland is working.

Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

If you have not told your doctor about any of the above, tell them before you start taking DAPA-TABS.

Taking other medicines

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

Some medicines may be affected by DAPA-TABS, or may affect how well it works. These include:

- lithium, a medicine used to treat mood swings and some types of depression, due to the risk of increased levels of lithium in the blood
- medicines used to treat mental illnesses such as some medicines for epilepsy, anxiety, schizophrenia and some other antidepressants (e.g. citalopram, escitalopram, tricyclic antidepressants, antipsychotic drugs, neuroleptics such as: droperidol, haloperidol, chlorpromazine, trifluoperazine, amisulpride, sulpiride, psychoanaleptics).
- antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine phosphate).
- other medicines used to treat high blood pressure (e.g. angiotensin converting enzyme (ACE) inhibitors), a fast or irregular heartbeat and other heart conditions.
- other diuretics, also known as "water" or "fluid" tablets (e.g. amiloride, spironolactone, triamterene).
- medicines used for heart rhythm problems (e.g. disopyramide, amiodarone hydrochloride,

sotalol hydrochloride, flecainide acetate)

- barbiturates, medicines used to treat epilepsy, produce calmness or to help you sleep
- medicines used to treat Alzheimer's disease, for example, donepezil
- 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 'auto-immune' 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 problems with the immune system
- amphotericin B (amphotericin) by IV, erythromycin by IV, clarithromycin (antibiotic medicines used to treat infections)
- medicines used to treat fungal infections, for example, fluconazole
- medicines used during scans to see the images of your body
- diphemanil metisulfate (used to treat excessive sweating)
- pentamidine isetionate (a medicine used to treat certain types of pneumonia)
- antihistamines used to treat allergic reactions, such as hay fever.
- medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone).

- medicines used to treat cancer (e.g. vandetanib, oxaliplatin).
- anagrelide (used to reduce elevated blood platelet counts)
- medicines used to treat gastrointestinal problems (e.g. cisapride, papaverine hydrochloride)
- medicines used to treat bacterial infections (e.g. Moxifloxacin, ciprofloxacin, clarithromycin, erythromycin by IV).
- allopurinol (a medicine used to treat gout).
- tetracosactide (tetracosactrin) (to treat Crohn's disease)
- methadone hydrochloride (used to treat addiction).
- cilostazol (used to treat cramp-like pain in the legs when you walk).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking DAPA-TABS.

For older people or children

Elderly people can generally use DAPA-TABS safely. However, some older people have reduced kidney function- in which case additional care may be required.

DAPA-TABS is not recommended for use in children.

How to take DAPA-TABS

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

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

How to take DAPA-TABS

Swallow the tablets whole with a glass of water.

When to take DAPA-TABS

Take DAPA-TABS at about the same time each morning.

DAPA-TABS can be taken with or without food.

If you forget to take it

If your next dose is less than 6 hours away, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

How long to take it for

To properly control your blood pressure, DAPA-TABS must be taken every day.

Keep taking DAPA-TABS for as long as your doctor recommends.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much DAPA-TABS.

Do this even if there are no signs of discomfort or poisoning.

Taking too much DAPA-TABS (an overdose) may cause low blood

pressure (hypotension). Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible.

You may need urgent medical attention.

While you are taking DAPA-TABS

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking DAPA-TABS.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking DAPA-TABS.

If you become pregnant while taking DAPA-TABS, tell your doctor immediately.

Visit your doctor regularly for check-ups.

Your doctor may want to check your blood pressure, kidney function, sodium levels and potassium levels while you are taking DAPA-TABS .

If you have to have any other blood tests, tell your doctor that you are taking DAPA-TABS.

DAPA-TABS may affect the results of some tests.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking DAPA-TABS as these may affect how DAPA-TABS is processed by your body. If you experience any of the following symptoms, you may be dehydrated because you are losing too much water:

- dry mouth or thirst
- fainting
- weakness
- tiredness or drowsiness

- muscle pain or cramps
- fast heartbeat
- passing less urine than normal

Things you must not do

Do not stop taking DAPA-TABS or change the dose without checking with your doctor.

Do not let yourself run out of DAPA-TABS over weekends or on holidays.

Do not use DAPA-TABS to treat any other conditions unless your doctor tells you to.

Do not give DAPA-TABS to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how DAPA-TABS affects you.

DAPA-TABS may cause tiredness, dizziness, or light-headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

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 .

Be careful getting up from a sitting or lying position.

Dizziness, light-headedness, or fainting may occur, especially when you get up quickly. Getting up slowly may help.

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 if you become sick and have severe or continuing vomiting or diarrhoea while taking DAPA-TABS.

The loss of additional water and certain salts such as potassium from

the body may make you feel faint, lightheaded, weak or sick.

DAPA-TABS may cause your skin to become more sensitive to the sun. If this happens you should stop taking DAPA-TABS and contact your doctor.

If you have these symptoms and they don't get better in a short time, then talk to your doctor.

Side effects

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

DAPA-TABS helps most people to lower their high blood pressure but it may have unwanted side effects in some people.

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- feeling sick or stomach upset, having an uncomfortable feeling after eating, vomiting, constipation, diarrhoea, or loss of appetite
- unusual tiredness or weakness, difficulty sleeping
- Muscle weakness, pain, tenderness, back pain, joint pain, cramp or tingling or numbness of the hands or feet (and particularly if at the same time you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (not known))

- skin rashes or other allergic reactions
- an increased risk of becoming dehydrated (in elderly patients and in patients with heart failure)
- dizziness or lightheaded-ness or feeling faint, especially when getting up from a sitting or lying position
- feeling nervous or anxious
- headache
- diarrhoea, constipation
- gout
- increased sensitivity to sunlight
- low potassium, magnesium or chlorine levels. Symptoms of low potassium can include a number of those listed above, and very occasionally this may be severe
- kidney disease
- inflammation of the pancreas
- hepatic encephalopathy (liver problems which affect the brain and the central nervous system)
- abnormal liver function
- if you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.
- changes in blood cells, such as thrombocytopenia (a decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopenia (a decrease of white blood cells which may cause unexplained fever, soreness of the throat or other flu-like symptoms) and anaemia (a decrease in red blood cells).
- high level of calcium in blood
- low blood pressure, unusual heartbeat
- blurred or changed vision, short sightedness (myopia)
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle closure glaucoma)
- dry mouth

- cystitis.
- erectile dysfunction

Most of these side effects are mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

Changes may occur in your laboratory parameters (blood tests) and your doctor may need to give you blood tests to check your condition. The following changes in laboratory tests may occur low potassium, magnesium, chloride or sodium in the blood, low sodium in the blood (that may lead to dehydration and low blood pressure), increase in uric acid (a substance which may cause or worsen gout), increase in blood glucose levels in diabetic patients, increased levels of liver enzymes.

Tell your doctor immediately or go to Accident and Emergency at the 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, mouth, tongue or throat which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.
- purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (A rare condition known as Stevens-Johnson Syndrome).
- toxic epidermal necrolysis
- a fast and irregular heartbeat
- severe blisters, skin rash, itching or other allergic reactions.
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking DAPA-TABS. This can lead to permanent vision loss, if not

treated. If you have a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

The side effects listed above are serious and require urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people. Also, some of side effects can only be found when your doctor does tests from time to time to check your progress.

After using DAPA-TABS

Storage

Keep DAPA-TABS where children cannot reach it.

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

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will 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 DAPA-TABS in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking DAPA-TABS, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DAPA-TABS is a 6.5 mm, normal convex, pink, film-coated tablet debossed "IE" over "2.5" on one side and "G" on the other.

Each pack contains 90 tablets.

Ingredients

The active ingredient in DAPA-TABS is indapamide hemihydrate.

Each tablet contains 2.5 mg of indapamide hemihydrate.

The tablets also contain the following inactive ingredients:

- lactose
- microcrystalline cellulose
- sodium starch glycollate
- croscarmellose sodium
- magnesium stearate
- Opadry Pink OY-6953 (ARTG PI No. 3110).

DAPA-TABS tablets contain lactose and trace quantities of sulfites.

Manufacturer

DAPA-TABS is made in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

Australian registration number:
DAPA-TABS - AUST R 62367

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