DAPA-TABS®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking DAPA-TABS?

DAPA-TABS contains the active ingredient indapamide hemihydrate. DAPA-TABS is used to treat high blood pressure (hypertension). For more information, see Section 1. Why am I taking DAPA-TABS? in the full CMI.

2. What should I know before I take DAPA-TABS?

Do not take if you have ever had an allergic reaction to DAPA-TABS or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take DAPA-TABS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DAPA-TABS and affect how it works. A list of these medicines is in Section <u>3. What if I am</u> taking other medicines? in the full CMI.

4. How do I take DAPA-TABS?

- The usual adult dose is one tablet daily, taken in the morning.
- Swallow the tablets whole with a glass of water.

More instructions can be found in Section 4. How do I take DAPA-TABS? in the full CMI.

5. What should I know while taking DAPA-TABS?

Things you should do	 Remind any doctor, dentist or pharmacist you visit 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. 	
Things you should 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. 	
Driving or using machines		
Drinking alcohol	ing alcohol • Tell your doctor if you drink alcohol.	
Looking after your medicine	 Keep DAPA-TABS in the pack until it is time to take it. Store below 30°C. 	

For more information, see Section 5. What should I know while taking DAPA-TABS? in the full CMI.

6. Are there any side effects?

Less serious side effects: feeling sick or stomach upset, vomiting, constipation, diarrhoea, or loss of appetite; unusual tiredness or weakness, difficulty sleeping; dizziness; fainting; muscle weakness, pain, joint pain, tingling or numbness of hands or feet; headache; gout; feeling nervous or anxious; headache; kidney disease; low blood pressure, unusual heartbeat; blurred or changed vision; dry mouth; erectile dysfunction; increased sensitivity to light; inflammation of pancreas; abnormal liver function; high levels of calcium in blood etc. Serious side effects: skin rash, itching or hives; swelling of the face, lips, mouth, tongue or throat; 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; fast and irregular heartbeat; severe blisters; decrease in vision or eye pain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

DAPA-TABS®

Active ingredient: indapamide hemihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking DAPA-TABS. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking DAPA-TABS.

Where to find information in this leaflet:

- 1. Why am I taking DAPA-TABS?
- 2. What should I know before I take DAPA-TABS?
- 3. What if I am taking other medicines?
- 4. How do I take DAPA-TABS?
- 5. What should I know while taking DAPA-TABS?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I taking DAPA-TABS?

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

DAPA-TABS is used either alone or in combination with other medicines in the treatment of high blood pressure (hypertension).

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.

There is no evidence that DAPA-TABS is addictive.

2. What should I know before I take DAPA-TABS?

Warnings

Do not take DAPA-TABS if:

- you have an allergic to:
 - o medicines containing indapamide

- sulfonamide or sulfa (sulpha) antibiotics, or thiazide diuretics (a type of "fluid" or "water" tablet)
- o any of the ingredients listed at the end of this leaflet
- Some of the symptoms of an allergic reaction may include:
 - o skin rash, itching or hives;
 - o swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;
 - o wheezing or shortness of breath.

Always check the ingredients to make sure you can take this medicine.

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
- o low potassium levels in your blood.
- the expiry date (EXP) printed on the pack has passed.

If you take DAPA-TABS after the expiry date, it may not work as well.

 the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking DAPA-TABS, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- have an intolerance to lactose.
- have any other medical conditions, especially the following:
 - o high or low levels of potassium, sodium, or other problems with salt balance
 - o systemic lupus erythematosus (SLE), a disease affecting the skin, joints and kidneys
 - o gout
 - o diabetes
 - o you have previously experienced an increased sensitivity to sunlight (photosensitivity reactions)
 - o heart rhythm problems
 - o kidney problems
 - o liver problems
 - o 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

DAPA-TABS[®]

- penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- o 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.

- take any medicines for any other condition
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. <u>Are there any side effects</u>?

Pregnancy and breastfeeding

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.

Older people

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

Children

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

3. What if I am taking other medicines?

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

Some medicines may interfere with DAPA-TABS and affect how 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 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 hav 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 (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.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DAPA-TABS.

4. How do I take DAPA-TABS?

How much to take

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

When to take DAPA-TABS

- Take DAPA-TABS at about the same time each morning.
- DAPA-TABS can be taken with or without food.

How to take

Swallow the tablets whole with a glass of water.

How long to take DAPA-TABS

- 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 forget to take DAPA-TABS

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.

If you take too much DAPA-TABS

If you think that you or anyone else has taken too much DAPA-TABS, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while taking DAPA-TABS?

Things you should 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.
- 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.

Call your doctor straight away if you:

- become pregnant while taking DAPA-TABS
- 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:
 - o dry mouth or thirst
 - o fainting
 - o weakness
 - o tiredness or drowsiness
 - o muscle pain or cramps
 - o fast heartbeat
 - o passing less urine than normal

Things you should 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 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.
- Dizziness or light-headedness may be worse if you take strong pain killers, barbiturates or other medicines for high blood pressure while being treated with DAPA-TABS.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DAPA-TABS affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking DAPA-TABS. Dizziness or light-headedness may be worse if you drink alcohol.

Looking after your medicine

- Keep DAPA-TABS in the pack until it is time to take it. If you take the tablets out of the pack they will not keep well.
- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take DAPA-TABS or it is out of date, take it to any pharmacy for safe disposal.

Do not take DAPA-TABS after the expiry date.

Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to lask your do ab

16

oct	the information below and, if you ne or or pharmacist if you have any fur it side effects.	
ess	serious side effects	
Les	s serious side effects	What to do
Sto •	mach and bowel related: feeling sick or stomach upset, having an uncomfortable feeling after eating, vomiting, constipation, diarrhoea dry mouth inflammation of the pancreas	Speak to your doctor if you have any of these less serious side effects.
Eye	related:	
•	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)	
Nei	rves, brain and mood related:	
•	dizziness or lightheaded-ness feeling nervous or anxious headache difficulty sleeping	
Kid	ney, bladder and liver related:	
•	kidney disease cystitis abnormal liver function hepatic encephalopathy (liver problems which affect the brain and the central nervous system)	

Muscle, bones and joints related:

- 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))
- Gout

Skin and hair related:

- skin rashes
- increased sensitivity to sunlight

Less serious side effects	What to do			
Blood, heart and circulation related:				
 changes in blood cells, such as thrombocytopenia (a decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopoenia (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). low blood pressure unusual heartbeat feeling faint, especially when getting up from a sitting or lying position 				
Hormones and metabolism related				
 high level of calcium in blood 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 an increased risk of becoming dehydrated (in elderly patients and in patients with heart failure) loss of appetite 				
General symptoms:				
unusual tiredness or weakness				
Immune system related:				
 other allergic reactions if you suffer from systemic lupus erythematous (a type of collagen disease), this might get worse. 				
Reproductive system related:				
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.

Serious side effects

Ser	ious side effects	What to do		
Allergy symptoms:		Call your		
•	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. severe blisters, skin rash, itching or other allergic reactions.	doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious		
Skin related:		side effects.		
•	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			
He	Heart related:			
•	a fast and irregular heartbeat			
Eye related:				
•	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.			

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DAPA-TABS contains

Active ingredient (main ingredient)	indapamide hemihydrate 2.5 mg		
Other ingredients (inactive ingredients)	 lactose microcrystalline cellulose sodium starch glycollate croscarmellose sodium magnesium stearate Opadry Pink OY-6953 (ID 3110) 		
Potential allergens	LactoseTrace quantities of sulfites		

Do not take this medicine if you are allergic to any of these ingredients.

What DAPA-TABS 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 (AUST R 62367).

Each pack contains 90 tablets.

Who distributes DAPA-TABS

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

This leaflet was prepared in October 2025.

DAPA-TABS® is a Viatris company trade mark

DAPA-TABS_cmi\Oct25/00