

SIDAPVIA[®] Film-Coated Tablet

Dapagliflozin/Sitagliptin (10 mg/100 mg)

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What SIDAPVIA is used for

SIDAPVIA is used with diet and exercise to control the level of blood sugar (glucose) in adults with type 2 diabetes mellitus.

Type 2 diabetes mellitus is a condition in which your body does not make enough insulin and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood and can lead to serious medical problems.

The main goal of treating type 2 diabetes is to control your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and amputation.

How SIDAPVIA works

SIDAPVIA contains two active ingredients, dapagliflozin and sitagliptin. Dapagliflozin belongs to a class of medicines called SGLT-2 (Sodium Glucose Cotransporter-2) inhibitors, and sitagliptin belongs to

a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors).

Dapagliflozin and sitagliptin work together to lower blood sugar levels in patients with type 2 diabetes mellitus.

Before you use SIDAPVIA

- When you must not use it

Do not use SIDAPVIA if:

- you are allergic to dapagliflozin or sitagliptin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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 or
- you may feel faint.

- Before you start to use it

Check with your doctor if you:

- have any allergies to any other medicines, foods, dyes, or preservatives
- have, or have had, any of the following medical conditions:
 - type 1 diabetes mellitus
 - kidney, liver, or pancreas problems
 - frequently get genital or urinary tract infections (infections of the bladder, kidney, or tubes that carry urine)

- an illness that will make you dehydrated such as diarrhoea or a severe infection
- diabetic ketoacidosis. This is a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood. You may notice this as rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.
- you are taking a medicine for high blood pressure or taking a water pill (diuretic).
- take any medicines for any other condition.

Your doctor will do some tests for kidney function at the start of treatment and regularly while you are on treatment.

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 'Side effects'.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

SIDAPVIA is not recommended for use during pregnancy. The safety of SIDAPVIA in pregnant women has not been established. If you become pregnant, stop taking SIDAPVIA and speak with your doctor immediately about the best way to control your blood glucose during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

SIDAPVIA should not be used while breastfeeding or if planning to breastfeed. It is not known if the active ingredients in SIDAPVIA will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking SIDAPVIA.

Children

SIDAPVIA is not recommended for use in children.

It has not been studied in children younger than 18 years old.

- 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.

Discard any other medicines containing dapagliflozin or sitagliptin that your doctor might have prescribed to you in the past and that you may still have in your possession.

SIDAPVIA contains dapagliflozin and sitagliptin. If you have more than one medicine containing dapagliflozin or sitagliptin in your possession, you may accidentally take too much (overdose).

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing dapagliflozin or sitagliptin.

Dapagliflozin and sitagliptin are sold separately as FORXIGA and JANUVIA in Malaysia. Your doctor or pharmacist will know which other medicines also contain dapagliflozin and sitagliptin and can tell you what to do.

Tell your doctor or pharmacist if you are taking any of the following:

- sulfonylureas
- insulin.

Especially tell your doctor:

- if you are taking lithium because SIDAPVIA can lower the amount of lithium in your blood.

SIDAPVIA may interfere with or affect how these medicines work, or these medicines may affect how SIDAPVIA works. Your doctor may need to adjust your dose of these medicines or change to a different medicine.

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

How to use SIDAPVIA

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 pack, ask your doctor or pharmacist for help.

- Swallow your SIDAPVIA tablet whole with a full glass of water.

- How much to use

- The dose of SIDAPVIA is one tablet once a day.

- When to use it

- SIDAPVIA should be taken at approximately the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help

you remember when to take the tablets.

- SIDAPVIA tablets can be taken with or without food.

- How long to use it

- **Continue taking SIDAPVIA for as long as your doctor tells you. Make sure you keep enough SIDAPVIA to last over weekends and holidays.**

SIDAPVIA helps control your condition, but does not cure it. Therefore, you must take SIDAPVIA every day.

- If you forget to use it

SIDAPVIA should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

- If you use too much (overdose)

If you think that you have used too much SIDAPVIA, you may need urgent medical attention.

You should immediately:

- 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.

While you are using it

- Things you must do

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking SIDAPVIA.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

It is important to have regular check-ups with your doctor or diabetes centre.

If you have diabetes, it is important to check your feet regularly and adhere to any other advice regarding foot care given by your doctor.

Tell your doctor if you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat. These symptoms could be a sign of diabetic ketoacidosis.

Talk to your doctor if you are having surgery (including dental surgery) to discuss when to stop taking SIDAPVIA and when to start taking it again.

If you need to have any medical tests while you are taking SIDAPVIA, tell your doctor.

SIDAPVIA may affect the results of some tests.

Visit your doctor regularly for checkups.

Your doctor may want to perform blood tests to check your kidneys, liver, heart, and levels of cholesterol and fats in your blood while you are taking SIDAPVIA.

Hypoglycaemia

SIDAPVIA does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines, such as insulin or a sulfonylurea.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Hyperglycaemia

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- forgetting to take SIDAPVIA
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery).

Your blood glucose may become difficult to control at these times.

If you become pregnant while taking SIDAPVIA, tell your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are using SIDAPVIA.

- Things you must not do

- Do not stop taking your medicine without checking with your doctor.
- Do not take SIDAPVIA to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.

- Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SIDAPVIA affects you.

Low blood sugar levels may slow your reaction time and affect your ability to drive or operate machinery.

Make sure you know how you react to SIDAPVIA before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

- Rash
- Irritation of the genitals caused by genital infection.
- Headache
- Stomach discomfort, vomiting or constipation.
- Back pain or muscle aches or pain in the joints, back, arm, or leg
- Signs of an infection of the breathing passages including runny nose, sore throat, cough, soreness in the back of the nose and throat and discomfort when swallowing, headache, flu-like symptoms.

What to do

Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Allergic reaction:

- Shortness of breath, wheezing or severe difficulty in breathing; shock, swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives on the skin, hayfever, or you may feel faint.

Hypoglycaemia:

- Low blood sugar (hypoglycaemia) may become worse in people who already take another medication to treat diabetes, such as sulfonylureas or insulin.

Signs of low blood sugar may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heartbeat, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar.

Skin-related:

- Develop blisters or the breakdown of your skin (erosion). These symptoms could be a sign of a skin reaction called bullous pemphigoid that can require treatment in a hospital.

Dehydration:

- Volume depletion (loss of needed fluids from the body; dehydration).

If you are unable to keep fluids down or if you have any of these symptoms of too much loss of body fluids while taking SIDAPVIA: dry sticky mouth, severe thirst, severe diarrhoea or vomiting, dizziness, or urinating less often than normal or not at all.

Infections-related:

- Genital infections. If you experience painful urination, soreness and more severe irritation or redness and swelling

of your genitals, or an unpleasant odour or discharge associated with your genitals.

- Urinary tract infection. If you have symptoms, such as burning or pain when you pass urine, more frequent or urgent need to urinate, fever, chills, or blood in the urine.
- If you experience pain or tenderness, redness, swelling of the genitals or the area from the genitals to the rectum, fever, and generally feeling unwell. These may be symptoms of a rare but serious and potentially life-threatening infection called Necrotising fasciitis of the perineum (Fournier's gangrene) and you will require prompt treatment.

Diabetic Ketoacidosis:

- In rare cases dapagliflozin, the active ingredient in SIDAPVIA, may cause a serious condition called diabetic ketoacidosis.

Symptoms of diabetic ketoacidosis may include feeling sick or being sick, difficulty breathing, severe thirst, feeling weak and tired, confusion, a sweet smell to your breath, a sweet or metallic taste in your mouth, a strange odour to your urine or sweat and frequent urination.

The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

Diabetes ketoacidosis is a life-threatening condition.

Pancreatitis:

- Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis.

Pancreatitis can be a serious, potentially life-threatening medical condition.

Kidney-related:

- Kidney problems (sometimes requiring dialysis)

What to do

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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

Storage and Disposal of SIDAPVIA

- Storage

- Keep your SIDAPVIA tablets in the blister until it is time to take them. If you take SIDAPVIA out of the blister it will not keep well.
- Keep it in a cool dry place where the temperature stays 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.

Keep it where young children cannot reach it.

- Disposal

If you no longer need to use this medicine or it is out of date, ask your pharmacist what to do with any medicine that is left over.

Do not use this medicine after the expiry date.

Product description

- What it looks like

SIDAPVIA 10 mg/100 mg film-coated tablets are yellow, oval shaped, approximately 8 mm x 15 mm, biconvex, film-coated tablets with “F M” debossed on one side and plain on the other side.

Available in blister packs of 7 or 28 tablets. Not all packs may be marketed.

- Ingredients

Active ingredients:

- Dapagliflozin 10 mg
- Sitagliptin 100 mg

Inactive ingredients:

Core tablet:

- croscarmellose sodium
- crospovidone
- microcrystalline cellulose
- mannitol
- magnesium stearate
- calcium hydrogen phosphate
- sodium stearyl fumarate

Film coating:

- polyvinyl alcohol
- titanium dioxide

- macrogol 3350
- talc
- iron oxide yellow

Potential allergens:

Not applicable

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

- MAL number

MALxxxxxx

Manufacturer

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Product Registration Holder

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