**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

S4

# AVAXIGA 5

**Contains sugar: Lactose Anhydrous 25 mg.**

# AVAXIGA 10

**Contains sugar: Lactose Anhydrous 50 mg.**

**Dapagliflozin**

**DO NOT USE AVAXIGA IF YOU HAVE TYPE 1 DIABETES MELLITUS.**

**AVAXIGA MUST NOT BE USED FOR THE TREATMENT OF ANY OTHER CONDITIONS EXCEPT FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS, HEART FAILURE AND CHRONIC KIDNEY DISEASE.**

**There have been reports of metabolic acidosis, including ketoacidosis, in patients taking AVAXIGA.**

**Metabolic acidosis is an imbalance of acids in your blood, shown on blood tests. It is a serious and sometimes fatal condition that requires hospitalisation. Risk factors for metabolic acidosis include sudden decrease of your insulin dose, prolonged fasting from food and drink, or increasing your insulin dose due to major surgery or serious illness, or alcohol abuse. Caution is advised when using AVAXIGA if you have these conditions.**

**Diabetic ketoacidosis is at type of metabolic acidosis. Diabetic ketoacidosis is an increase of ketone bodies in your blood or urine, shown on blood or urine tests.**

**Risk factors for diabetic ketoacidosis include pancreatic conditions, such as inflammation of the pancreas or previous pancreatic surgery. Do not use AVAXIGA if you have these conditions.**
**Metabolic acidosis, including diabetic ketoacidosis, may occur in patients with type 2 diabetes mellitus with normal (blood glucose test result below 14 mmol/l) or high blood sugar levels who are treated with AVAXIGA. Contact a doctor or the nearest hospital straight away if you have the following symptoms even if your blood sugar levels are normal: nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.**

**Read all of this leaflet carefully before you start taking AVAXIGA.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AVAXIGA** 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 **AVAXIGA** is and what it is used for
2. What you need to know before you take **AVAXIGA**
3. How to take **AVAXIGA**
4. Possible side effects
5 How to store **AVAXIGA.**

6. Contents of the pack and other information

1. **What AVAXIGA is and what it used for:**

   **AVAXIGA** contains the active substance dapagliflozin. It belongs to a group of medicines called "oral anti-diabetics". These are medicines taken by mouth tor diabetes.

   **AVAXIGA** is used if your type 2 diabetes cannot be controlled with different medicines for diabetes, diet and exercise.

   Your doctor may ask you to take **AVAXIGA** alone or with other diabetes medicines.

   **AVAXIGA** increases the amount of sugar excreted by your kidneys.

   **AVAXIGA** is also used for prevention and treatment of heart failure (when the heart does not pump enough blood that the body needs).

   **AVAXIGA** is not recommended for children and young people under 18 years.

   It is important to keep following the advice about diet and exercise given to you by your doctor, nurse or pharmacist.

2. **What you need to know before you take AVAXIGA:**

**Do not take AVAXIGA:**

- if you are allergic (hypersensitive) to dapagliflozin or any of the other ingredients of **AVAXIGA**. (listed in section 6).
- if you have moderate or severe kidney disease or you are on dialysis.
- if you have type 1 diabetes - the type that usually starts when you are young, and your body does not produce any insulin.
- if you are pregnant (see Pregnancy and Breastfeeding).

- if you are breast-feeding (see Pregnancy and Breastfeeding).

**Warnings and precautions**

**Take special care with AVAXIGA:**

- If you have diabetes and experience 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 or rapid weight loss.
    - The above symptoms could be a sign of “diabetic ketoacidosis” – a rare but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests.
    - 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.
    - When you are treated with **AVAXIGA**, diabetic ketoacidosis can occur even if your blood sugar is normal.
- if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier’s gangrene which destroys the tissue under the skin. Fournier’s gangrene has to be treated immediately.

- if you have a liver problem
- if you are on medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). See ‘Other medicines and **AVAXIGA**’.
- if you have very high levels of sugar in your blood which may make you dehydrated (lose too much body fluid). Tell your doctor before you start taking **AVAXIGA** if you have any of these signs.
- if you have or develop nausea (feeling sick), vomiting or fever or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking **AVAXIGA** until you recover to prevent dehydration.
- if you often get infections of the urinary tract.

Do not stop taking this medicine without speaking to your doctor.

**Other medicines and AVAXIGA:**

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

Tell your doctor:

- if you are taking ketoconazole (medication for fungal infections).
- if you are taking a water pill (diuretic) - you may be more likely to lose fluid from your body (get dehydrated). Your doctor may change your dose.
- if you are taking other medicines that lower the amount of sugar in your blood - such as insulin or a "sulfonylurea" medicine. Your doctor may want

to lower your dose of these other medicines, to stop you from getting low blood sugar (hypoglycaemia).

**Pregnancy and breastfeeding and fertility:**

You should not take **AVAXIGA** if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking/ receiving **AVAXIGA**.

**Driving and using machines:**

Taking **AVAXIGA** with other medicines or insulin used to treat your diabetes can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines. Do not drive or use any tools or machines if you feel dizzy while taking **AVAXIGA**. It is not always possible to predict to what extent **AVAXIGA** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of how **AVAXIGA** affects you.

**AVAXIGA contains:**

**AVAXIGA** contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **AVAXIGA**.

3. **How to take AVAXIGA:**

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

Always take **AVAXIGA** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- **The usual dose is:** one 10 mg tablet each day.
- Your doctor will prescribe the strength that is right for you.
- Your doctor will tell you how long your treatment with **AVAXIGA** will last.
- Do not stop treatment early.
- If you have the impression that the effect of **AVAXIGA** is too strong or too weak for you, tell your doctor or pharmacist.
- Swallow the tablet whole with some water.
- You can take your tablet with or without food.
- You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.
- Your doctor may prescribe **AVAXIGA** together with other medicines to lower the amount of sugar in your blood.

**Use in children:**

- **AVAXIGA** is not recommended for children or young people under18 years old.

Diet and exercise:

- To control your diabetes, you still need to diet and exercise, even when you are taking this medicine. So, it is important to keep following the advice about diet and exercise from your health care professional. In particular, if you are following a diabetic weight control diet, keep on with this while you are taking **AVAXIGA**.

**If you take more AVAXIGA than you should:**

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

**If you forget to take a dose of AVAXIGA:**

Try to take **AVAXIGA** as prescribed by your healthcare professional. However, if you miss a dose, take your missed dose as soon as you remember, if within a few hours after missing a dose. If it is nearly time for your next dose, skip the missed dose. Then take your next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking AVAXIGA:**

Do not stop taking **AVAXIGA** without talking to your doctor first. If you have the impression that the effect of **AVAXIGA** is too strong or too weak, talk to your doctor or pharmacist.

## 4. Possible side effects

**AVAXIGA can have side effects.**

**Not all side-effects reported for this medicine are included in this leaflet.**

**Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

**If any of the following happens, stop taking AVAXIGA and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- If you have a hypersensitivity (allergic) reaction
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting

These are very serious side effects. If you have them, you may have had a serious reaction to **AVAXIGA.** 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:**

- Angioedema

  These are signs of angioedema:

  - swelling of the face, tongue, or throat
  - difficulties swallowing
  - hives and breathing problems

- Diabetic ketoacidosis

  These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):

  - increased levels of “ketone bodies” in your urine or blood
  - 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.
  - rapid weight loss.

- necrotising fasciitis of the perineum or Fournier's gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus, seen very rarely.
- urinary tract infection

  These are signs of a severe infection of the urinary tract:

  - fever and/or chills
  - burning sensation when passing water (urinating)
  - pain in your back or side

These are serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

Frequent:

- low blood sugar levels (hypoglycaemia)

  These are the signs of low blood sugar:

  - shaking, sweating, feeling very anxious, fast heartbeat
  - feeling hungry, headache, change in vision.
  - a change in your mood or feeling confused.
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- passing more water (urine) than usual or needing to pass water more often
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment.

- dizziness
- rash

Less Frequent:

- loss of too much fluid from your body (dehydration, signs may include very dry or sticky mouth, passing little or no urine or fast heartbeat)
- thirst
- constipation
- awakening from sleep at night to pass urine.
- dry mouth
- weight decreased.
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment.
- increases in urea (shown in laboratory blood tests)
- excessive sweating

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of KIDDOFEN.

Contact Innovata Pharmaceuticals:

Email: regulatory@innovata.co.za

Tel: +27 86 999 0912

## 5. How to store AVAXIGA

**STORE ALL MEDICINE OUT OF REACH OF CHILDREN**

Store **AVAXIGA** at or below 30 °C in an outer carton. Protect from light and moisture.

Do not use this medicine after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

## 6. Contents of the pack and other information

**What AVAXIGA contains:**

**The active substance is:** Dapagliflozin.

**The other ingredients are:**

Acetone

Anhydrous Lactose

Colloidal Silicon Dioxide

Low Substituted Hydroxypropyl Cellulose

Magnesium Stearate

Microcrystalline Cellulose

Sepitrap

Opadry II Yellow

- Iron Oxide Yellow
- Macrogol
- Talc
- Titanium Dioxide

**What AVAXIGA looks like and contents of the pack**

**AVAXIGA 5**

Yellow coloured biconvex, round shaped, film coated tablets with “120” engraved on one side and plain on another side.

**AVAXIGA 10**

Yellow coloured biconvex, diamond shaped film coated tablets with “121” engraved on one side and plain on another side.

30’s- 3x10 plain aluminum foil blisters, with an Alu-Alu film, in an outer mono carton with a package insert.

**Holder of Certificate of Registration**

Innovata Pharmaceuticals Pty Ltd

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Building D

Ormonde

Johannesburg

2091

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AVAXIGA 5: A 57/21.2/0651

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**Access to the corresponding Professional information is contained in the packaging.**

Follow the link for the corresponding Professional Information for Avaxiga: pi-pil-repository.innovata.co.za,

Alternatively, please scan the QR code below:

