

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

OLFID 5 mg film-coated tablets

OLFID 10 mg film-coated tablets

Dapagliflozin

Sugar free.

Read all of this leaflet carefully before you start taking OLFID

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OLFID 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 OLFID is and what it is used for
2. What you need to know before you take OLFID
3. How to take OLFID
4. Possible side effects
5. How to store OLFID
6. Contents of the pack and other information.

1. What OLFID is and what it is used for

OLFID contains the active ingredient dapagliflozin, which belongs to a group of medicines called oral antidiabetics. OLFID 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 OLFID alone or with another diabetes medicines.
- OLFID increases the amount of sugar excreted by your kidneys.

OLFID is not recommended for children and young people under the age of 18 years.

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

2. What you need to know before you take OLFID

Do not take OLFID:

- If you are hypersensitive (allergic) to dapagliflozin or any of the other ingredients of OLFID listed in section 6 of this leaflet.
- If you have kidney disease or are on dialysis.
- If you have type 1 diabetes mellitus.
- If you are pregnant or breastfeeding.

Warnings and precautions

DO NOT USE OLFID IF YOU HAVE TYPE 1 DIABETES. OLFID IS NOT INDICATED FOR USE IN WEIGHT CONTROL PROGRAMMES. OLFID MUST NOT BE USED FOR THE TREATMENT OF ANY OTHER CONDITIONS EXCEPT TYPE 2 DIABETES.

Contact a doctor or the nearest hospital straight away:

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 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 OLFID, diabetic ketoacidosis can occur even if your blood sugar is normal.

Tell your doctor or pharmacist if:

- You are going to have surgery.
- You are eating less due to illness, surgery or you are dieting.
- You have or have previously had pancreas problems.
- You drink large amounts of alcohol.
- You often get infections of the urinary tract.

Tell your doctor or pharmacist immediately if you develop a combination of pain, tenderness, redness or swelling in your genital area or the area between the genitals and anus, with fever or a general unwell feeling. 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 your skin. Fournier's gangrene has to be treated immediately.

Take special care with OLFID:

- If you have kidney problems. Your doctor may prescribe you a different medicine or monitor your kidney function while you are being treated with OLFID.
- If you have liver problems.
- If you are taking medicines to lower your blood pressure or a diuretic medicine (water pill) and have a history of low blood pressure.
- If your blood sugar levels are very high, as this may cause your body to dehydrate (lose too much water and salts).
- If you have or develop diarrhoea, nausea (feeling sick) or vomiting (being sick). This may also cause your body to dehydrate and your doctor may ask you to stop taking OLFID until you recover.

- If you are elderly.

Diabetes and foot care

As a diabetic patient, it is important to check your feet regularly and adhere to any other advice regarding foot care given to you by your doctor, pharmacist or other health care provider.

Kidney function

If you have diabetes, your kidneys should be checked before you start taking and whilst you are on OLFID.

Urine glucose

Due to the way OLFID works, your urine will test positive for sugar while you are taking OLFID.

Children and adolescents

OLFID is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and OLFID

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

Tell your doctor:

- If you are taking diuretic medicine (water pill) (used to lower blood pressure or remove excessive water from the body).
- If you are taking other medicines to lower your blood sugar levels, such as insulin or a group of medicines called sulphonylureas. Your doctor may want to lower the dose of your other medicines to prevent hypoglycaemia (too low levels of sugar in the blood).

Pregnancy and breastfeeding

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 health care provider for advice before taking OLFID.

Do not take OLFID if you are pregnant or breastfeeding.

Driving and using machines

OLFID has no or negligible influence on the ability to drive and use machines. Taking OLFID with other medicines called sulphonylureas or with insulin can cause very low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and a change in your vision. This may affect your ability to drive and use machines. Do not drive or use any tools or machines, until you know how OLFID affects you, or if you feel dizzy taking OLFID.

3. How to take OLFID

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

Always take OLFID 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 OLFID tablet each day.

Your doctor may prescribe you a different strength that is right for you.

Your doctor may prescribe you OLFID together with other medicines to lower your blood sugar levels.

Your doctor will tell you how long your treatment with OLFID will last. Do not stop treatment early.

If you have the impression that the effect of OLFID is too strong or too weak, tell your doctor or pharmacist.

Swallow the tablet whole with water.

OLFID can be taken 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.

To control your diabetes, you still need to diet and exercise, even when you are taking OLFID. It is important to keep following the advice about diet and exercise from your health care provider in particular. If you are following a diabetic weight control diet, keep on with this while you are taking OLFID.

If you take more OLFID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining OLFID with you so the doctor will know what you have taken.

If you forget to take OLFID

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking OLFID

Do not stop taking OLFID unless your doctor tells you to. If you have diabetes, your blood sugar may increase when you stop taking OLFID. If you have any further questions on the use of OLFID, ask your doctor or pharmacist.

4. Possible side effects

OLFID can have side effects.

Not all side effects reported for OLFID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OLFID, please consult your health care provider for advice.

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

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to OLFID. 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:

- urinary tract infection (causing fever and/or chills, a burning sensation while urinating, pain in your back or side and sometimes blood in your urine);
- passing more water (urine) than usual or needing to pass water more often, painful or difficult urination, urinating more frequently during the night;
- diabetic ketoacidosis (causing nausea (feeling sick), vomiting (being sick), pain in your stomach area, tiredness, excessive thirst, passing of large volumes of urine, 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 along with fever and a general unwell feeling;
- low blood sugar levels, especially when taking OLFID with insulin or a sulphonylurea (causing shaking, sweating, fast heartbeat, headache, changes in vision, a change in your mood and confusion);

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour);
- high glucose (sugar) levels in the urine when tested;
- dizziness;
- back pain.

Less frequent side effects:

- 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);
- decreased blood pressure;
- constipation, dry mouth, thirst;
- excessive sweating;
- genital itching;
- changes in the amount of cholesterol or fats in your blood (shown in tests);
- changes in test results when testing the amount of red blood cells in your blood;
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment;
- changes in test results when testing your blood creatinine or urea levels;
- decreased weight.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of OLFID.

5. How to store OLFID

- Store at or below 25 °C.
- Blister strips: Keep in the outer carton until required for use.
- HDPE containers: Keep in the original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OLFID contains

The active substance is dapagliflozin.

OLFID 5: Each film-coated tablet contains 5 mg dapagliflozin.

OLFID 10: Each film-coated tablet contains 10 mg dapagliflozin.

The other ingredients are colloidal silicon dioxide (E551), crospovidone (E1202), magnesium stearate (E572), microcrystalline cellulose (E460(i)), Opadry Yellow (containing iron oxide yellow (E172), macrogol (E1521), talc (E553b), titanium dioxide (E171)), polyvinyl alcohol (E1203) and sodium lauryl sulfate.

What OLFID looks like and contents of the pack

OLFID 5: Yellow coloured, round, biconvex, film-coated tablets debossed with "D1" on one side and "M" on other side.

OLFID 10: Yellow coloured, diamond, biconvex, film-coated tablets debossed with "D2" on one side and "M" on other side.

Aluminium/aluminium blister strips packed in an outer carton or white opaque HDPE containers

containing 30 tablets, or HDPE containers containing 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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