

## **Package leaflet: Information for the patient**

### **Zensita-D (50 mg + 5 mg) & (100 mg + 10 mg) film-coated tablets**

sitagliptin/dapagliflozin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Zensita-D is and what it is used for
2. What you need to know before you take Zensita-D
3. How to take Zensita-D
4. Possible side effects
5. How to store Zensita-D
6. Contents of the pack and other information

#### **1. What Zensita-D is and what it is used for**

Zensita-D contains the active substances sitagliptin and dapagliflozin. Each belongs to a group of medicines called “oral anti-diabetics”. These medicines are taken by mouth for diabetes.

Sitagliptin and Dapagliflozin are indicated for the treatment of type 2 diabetes mellitus inadequately controlled on Metformin monotherapy.

If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar in your blood.

#### **Zensita-D is used to treat type 2 diabetes when:**

- sitagliptin or dapagliflozin alone, together with metformin and/or sulphonylurea cannot control your diabetes.
- you are already being treated with sitagliptin and dapagliflozin as single tablets. Your doctor may ask you to switch to this medicine.
- It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

#### **2. What you need to know before you take Zensita-D**

***Do not take Zensita-D:***

- if you are allergic to sitagliptin, dapagliflozin or any of the other ingredients of this medicine (listed in section 6).
- if you have had a serious allergic reaction to any other similar medicines (for example DPP-4 inhibitors like sitagliptin, linagliptin, alogliptin, or SGLT2 inhibitors like canagliflozin, empagliflozin) that you take to control your blood sugar.

Do not take Zensita-D if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist, or nurse before taking this medicine.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Zensita-D, and during treatment:

- if you have or have had a disease of the pancreas called pancreatitis. Possible signs of pancreatitis are listed in section 4.
- if you are on medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). For more information, see section “Other medicines and Zensita-D” below.
- if you have very high levels of sugar in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed at the top of section 4. Tell your doctor before you start taking Zensita-D 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 Zensita-D until you recover to prevent dehydration.
- if you have moderate or severe liver problem.
- 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, contact a doctor or the nearest hospital straight away. These 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.
- if you have “type 1 diabetes” your body does not produce any insulin. Zensita-D should not be used to treat this condition.
- if you have or have had a serious hypersensitivity (allergic) reaction or is suspected. Signs of a serious allergic reaction are listed in section 4.
- if you often get infections of the urinary tract.
- if you have a history of serious heart disease.
- if you suffer from heart failure or you have other risk factors for developing heart failure such as problems with your kidneys. Your doctor will advise you of the signs and

symptoms of heart failure. Symptoms can include, but are not limited to, increasing shortness of breath, rapid increase in weight and swelling of the feet (pedal oedema). You should call your doctor, pharmacist or nurse immediately if you experience any of these symptoms.

- if you have severe joint pain.
- if your body's ability to fight infections is reduced, for example if you have a disease like AIDS or have undergone an organ transplant.
- if you are taking a medicine to lower your blood sugar, such as sulphonylureas (see "Other medicines and Zensita-D").
- If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Zensita-D.
- Diabetic skin lesions (skin damage such as sores or ulcers) are a common complication of diabetes. Rash has been seen with both sitagliptin and dapagliflozin when given separately (see section 4). You are advised to follow the recommendations for skin care that you are given by your doctor or nurse. Contact your doctor if you encounter blistering of the skin, as it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Zensita-D.
- Like for all diabetic patients it is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.
- Talk to your doctor immediately 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.

### **Kidney function**

Your kidneys should be checked before you start taking Zensita-D. During treatment with this medicine, your doctor will check your kidney function once a year or more frequently if you have worsening kidney function.

### **Urine tests**

Because of how Zensita-D works, your urine will test positive for sugar while you are on this medicine.

### **Children and adolescents**

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

### **Other medicines and Zensita-D**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

***Especially tell your doctor:***

- if you are taking a medicine used to increase the amount of water you pass out of the body (diuretic). Your doctor may ask you to stop taking Zensita-D. Possible signs of losing too much fluid from your body are listed at the top of section 4.
- if you are taking another medicine that lowers the amount of sugar in your blood such as a sulphonylurea (for example glimepiride). Your doctor may want to lower the dose of this other medicine, to prevent you from getting low blood sugar levels (hypoglycaemia).
- if you are using medicines containing any of the following active substances, that might have an effect on the breakdown of Zensita-D in your body. Your doctor may ask you to check your blood sugar levels more often while taking these medicines.
- Carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- Dexamethasone – a steroid medicine. This may be used to treat inflammation in different body parts and organs.
- Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.
- Ketoconazole. This may be used to treat fungal infections.
- Diltiazem. This is a medicine used to treat angina (chest pain) and lower blood pressure.
- If any of the above apply to you (or if you are not sure), talk to your doctor before taking Zensita-D.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Zensita-D is not recommended during pregnancy and your doctor will ask you to stop taking this medicine if you become pregnant. Talk to your doctor about the best way to control your blood sugar while you are pregnant.

You should not use Zensita-D if you are breast-feeding. It is not known if this medicine passes into human breast milk. Talk to your doctor if you would like to or are breast-feeding before taking this medicine.

**Driving and using machines**

Zensita-D is not expected to affect you being able to drive a car or use any tools or machines. If you feel dizzy while taking this medicine, do not drive or use any tools or machines. Taking this medicine together with another medicine that lowers your blood sugar, such as a sulphonylurea, can cause too low blood sugar levels (hypoglycaemia). This may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.

Zensita-D contains lactose

Zensita-D contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Zensita-D contains sodium

Zensita-D contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium free’.

### **3. How to take Zensita-D**

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

#### **How much to take**

- The recommended dose is one tablet once or twice daily.

The dosage of Sitagliptin and Dapagliflozin should be individualized on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 100 mg Sitagliptin and 10 mg Dapagliflozin. Initial combination therapy or maintenance of combination therapy should be individualized and left to the discretion of the health care provider.

#### ***Taking this medicine***

- Swallow the tablet whole with half a glass of 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 other medicines to lower the amount of sugar in your blood.

Remember to take other medicine(s) as your doctor has told you. This will help get the best results for your health.

#### **Diet and exercise**

To control your diabetes, you still need to keep 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 doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking Zensita-D.

#### ***If you take more Zensita-D than you should***

If you take more Zensita-D tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

#### **If you forget to take Zensita-D**

*What to do if you forget to take a tablet.*

- If it is less than 12 hours since you should have taken your dose, take a dose of Zensita-D as soon as you remember. Then take your next dose at the usual time.
- If it is more than 12 hours since you should have taken your dose, skip the missed dose.
- Then take your next dose at the usual time.
- Do not take a double dose of Zensita-D to make up for a forgotten dose.
- If you stop taking Zensita-D

Do not stop taking Zensita-D without talking to your doctor first. Your blood sugar may increase without this medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Zensita-D and see a doctor straight away if you notice any of the following serious side effects:

- Symptoms of a serious allergic reaction (anaphylactic reaction, angioedema) seen rarely, (may affect up to 1 in 1 000 people), which may include:
  - rash,
  - raised red patches on your skin (hives),
  - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.
  - Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.
- Pancreatitis, seen uncommonly (may affect up to 1 in 100 people): severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas.

Dehydration, (loss of too much fluid from your body), seen uncommonly.

*These are signs of dehydration:*

- very dry or sticky mouth, feeling very thirsty,
  - feeling very sleepy or tired,
  - passing little or no water (urine),
  - fast heartbeat.
- Urinary tract infection, seen commonly (may affect up to 1 in 10 people).

*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.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

- Low blood sugar levels (hypoglycaemia), seen very commonly (may affect more than 1 in 10 people) if used with other diabetes medicines known to cause hypoglycaemia.

*These are the signs of low blood sugar:*

- shaking, sweating, feeling very anxious, fast heart beat,
- feeling hungry, headache, change in vision,
- a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above.

- Diabetic ketoacidosis, seen rarely.

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

- increased levels of “ketone bodies” in your urine or blood,
- 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.

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with Zensita-D.

- 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 (may affect up to 1 in 10 000 people).

Stop taking Zensita-D and see a doctor or nurse straight away, if you notice any of the serious side effects above.

Other side effects when taking Zensita-D alone or in combination with metformin:

**Very common**

- upper respiratory tract infection including:
  - infection of the upper chest or lungs,
  - infection of the sinuses with a feeling of pain and fullness behind your cheeks and eyes (sinusitis),
  - inflamed nose or throat (nasopharyngitis) (signs of this may include a cold or a sore throat).

**Common**

- 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
- tiredness
- severe joint pain (arthralgia)
- stomach ache and indigestion (dyspepsia)
- nausea
- diarrhoea
- inflamed stomach or gut usually caused by an infection (gastroenteritis)
- headache, muscle pain (myalgia)
- vomiting, inflammation of the stomach (gastritis)
- rash

**Uncommon**

- 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)
- skin rash that may include raised bumps, skin irritation, or unpleasant itchiness
- difficulties in getting or maintaining an erection (erectile dysfunction)
- fungal infection
- hypersensitivity reactions
- itching in the genital area (pruritus genital or vulvovaginal pruritus) or discomfort while urinating

**Not known (frequency cannot be estimated from the available data)**

- blistering of the skin (bullous pemphigoid)

***Reporting of side effects***

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the tab “Safety Reporting” located on the top of the home page.

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

**5. How to store Zensita-D**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blister and carton after ‘EXP’. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information**

***What Zensita-D contains***

- The active substances are sitagliptin and dapagliflozin.
  - Each tablet contains sitagliptin+ dapagliflozin (50+5) mg / (100+10) mg.
- 10 Blister strips of 10 tablets each

**Marketing Authorisation Holder**

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