

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DIBESTOR 25 mg film-coated tablet

DIBESTOR 50 mg film-coated tablet

DIBESTOR 100 mg film-coated tablet

Sitagliptin hydrochloride monohydrate

Sugar free.

Read all of this leaflet carefully before you start taking DIBESTOR

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



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1. What DIBESTOR is and what it is used for

DIBESTOR improved the levels of insulin after a meal.

DIBESTOR is a type of medicine that is called a dipeptidyl peptidase-4 inhibitors (DDP-4) that lowers blood sugar levels in patients with type 2 diabetes mellitus.

Type 2 diabetes is also called non-insulin-dependent diabetes mellitus.

DIBESTOR can be used alone or in combination with certain other medicines that lower blood sugar levels, along with a recommended diet and exercise program.

2. What you need to know before you take DIBESTOR

Do not take DIBESTOR:

- If you are hypersensitive (allergic) to sitagliptin hydrochloride monohydrate or any of the other ingredients of **DIBESTOR** (listed in section 6).
- If you have type 1 diabetes

Warnings and precautions

Special care should be taken with **DIBESTOR**:

- If you have any allergies

Tell your doctor if you have or have had:

- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- any past or present kidney problems
- a disease / inflammation of the pancreas (such as pancreatitis)



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- gallstones, very high levels of triglycerides (a form of fat) in your blood or alcohol dependence. These medical conditions can increase your risk of getting pancreatitis (see section 4).

Call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis or if you develop a skin condition that has large, fluid-filled blisters (bulbous pemphigoid).

Children and adolescents

DIBESTOR has not been studied in children under 18 years of age. Therefore, children and adolescents below 18 years should not use this medicine.

Other medicines and DIBESTOR

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 digoxin (a medicine used to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked.

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 this medicine.

You should not take this medicine during pregnancy.

You should not take this medicine if you are breast-feeding or plan to breast-feed as it is not known if this medicine passes into breast milk.



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Driving and using machines

DIBESTOR can cause dizziness and/or drowsiness. It is not always possible to predict to what extent **DIBESTOR** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **DIBESTOR** affects them as **DIBESTOR** can cause dizziness and /or drowsiness.

3. How to take DIBESTOR

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

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

The usual dose when taken with other medicines used to treat diabetes is one 100 mg film coated tablet. **DIBESTOR** can be taken with or without food.

Your doctor may prescribe a different dose depending on your condition.

Your doctor will tell you how long your treatment with **DIBESTOR** will last. Do not stop treatment early. If you have the impression that the effect of **DIBESTOR** is too strong or too weak, tell your doctor or pharmacist.

If you take more DIBESTOR than you should

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



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If you forget to take DIBESTOR

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DIBESTOR can have side effects.

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

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

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).
- If you have a serious allergic reaction, including hives, rash, blisters on the skin/peeling skin and swelling of the lips, face, tongue and throat that may cause difficulty in breathing or swallowing

These are all very serious side effects. If you have them, you may have had a serious reaction to **DIBESTOR**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:



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Frequent

- Low blood sugar
- Flatulence
- Nausea
- Headache
- Arm or leg pain
- Foot swelling
- Painful joints mostly in the hips, knees and spine

Less frequent

- Diarrhoea
- Vomiting
- Constipation
- Abdominal pain
- Dizziness
- Drowsiness

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

DIBESTOR.



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5. How to store DIBESTOR

Store all medicines out of reach of children.

- Store at or below 25 °C
- Keep the blister in the outer carton
- There are no special storage instructions for **DIBESTOR**
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the carton

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DIBESTOR contains

- The active substance is sitagliptin hydrochloride monohydrate

The other ingredients are calcium phosphate anhydrous, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, sodium stearyl fumarate, macrogol 4000, polyvinyl alcohol, red iron oxide E172, talc, titanium dioxide, yellow iron oxide E172.

What DIBESTOR looks like and contents of the pack

DIBESTOR 25 mg film-coated tablets

Film-coated, round, biconvex, orange tablets, one side engraving "25".

DIBESTOR 50 mg film-coated tablets

Film-coated, round, biconvex, orange tablets, one side engraving "50".



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Applicant: Trinity Pharma (Pty) Ltd

Product name (number): Dibestor 25 (56/21.2/1044), Dibestor 50 (56/21.2/1045) and Dibestor 100 (56/21.2/1046)

DIBESTOR 100 mg film-coated tablets

Film-coated, round, biconvex, orange tablets, one side engraving "100".

DIBESTOR is packed in blisters of PVC/PVDC/Aluminium in outer carton.

The blisters container 7 or 10 tablets and the cartons can contain 14, 28, 30, 56, 60, 90, 120 tablets. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

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South Africa

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Registration number

Dibestor 25 56/21.2/1044

Dibestor 50 56/21.2/1045

Dibestor 100 56/21.2/1046

Access to the corresponding Professional Information

The PI is contained in the packaging of this medicine



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