

DIASIT 25 (Sitagliptin Film Coated Tablets 25mg)

DIASIT 50 (Sitagliptin Film Coated Tablets 50mg)

DIASIT 100 (Sitagliptin Film Coated Tablets 100mg)

Sitagliptin Hydrochloride Monohydrate equivalent to Sitagliptin 25mg, 50mg and 100mg

What is in this leaflet

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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What is DIASIT used for

DIASIT (Sitagliptin hydrochloride monohydrate) is a tablet that contains 25, 50 or 100mg of Sitagliptin as the active ingredient.

> DIASIT helps to improve the levels of insulin after a meal

> DIASIT decreases the amount of sugar made by the body.

> DIASIT works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of help in lowering blood sugar. DIASIT also lowers blood sugar between meals.

> DIASIT by itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not work when your blood sugar is low.

How DIASIT works

DIASIT is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl

peptidase-4 inhibitors) that lowers blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin dependent diabetes mellitus, or NIDDM.

Why has my doctor prescribed DIASIT?

Your doctor has prescribed DIASIT to help lower your blood sugar, which is too high because of your type 2 diabetes. DIASIT can be used alone or in combination with certain other medicines that lower blood sugar, along with a recommended diet and exercise program.

What is type 2 diabetes

Type 2 diabetes 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. This can lead to serious medical problems.

The main goal of treating diabetes is to lower 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.

High blood sugar can be lowered by diet and exercise, and by certain medicines.

Before you use DIASIT

-When you must not use it

Do not take DIASIT if you are allergic to any of the ingredients of DIASIT.

-Before you start to use it

Tell your doctor if you have or have had:

> Type 1 diabetes

> Diabetic ketoacidosis (increased ketones in the blood or urine)

> Any kidney problems, or any past or present medical problems

> An allergic reaction to DIASIT

> Gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis.

-Taking other medications

DIASIT may be taken with most medicines. Tell your doctor about all the medicines you take. This includes prescription and non-prescription medicines, and herbal supplements.

In particular, tell your doctor:

> If you are taking digoxin (a medicine used to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with DIASIT.

How to use DIASIT

-How much to use and When to use it

Take DIASIT exactly as your doctor has prescribed. The recommended dose is to take:

> One 100mg tablet

> once a day

> by mouth, with or without food

If you have kidney problems, your doctor may prescribe lower doses.

Your doctor may prescribe DIASIT along with certain other medicines that lower blood sugar.

-How long to use it

Continue to take DIASIT as long as your doctor prescribes it so you can continue to help control your blood sugar. Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and

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weight loss program while taking DIASIT.

-If you forget to use it

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 of DIASIT.

-If you use too much (overdose)

If you take more than the prescribed dosage of DIASIT, contact your doctor immediately.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking DIASIT.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

DO not give DIASIT to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving DIASIT. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking DIASIT and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Cases of skin reaction called bullous pemphigoid that can require treatment in a hospital have been

reported in patients receiving DIASIT. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking DIASIT.

Use in children

DIASIT is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. DIASIT has not been studied in children younger than 10 years of age.

Use in the elderly

In studies, DIASIT worked well in and is well-tolerated by older adult patients. No dosage adjustment is necessary based on age.

Use in pregnancy and breast-feeding

Women who are pregnant or plan to become pregnant should consult with their doctor before taking DIASIT. DIASIT is not recommended for use during pregnancy.

It is not known if DIASIT passes into breast milk. You should not use DIASIT if you are breast feeding or plan to breastfeed.

Can I drive or operate machinery while using DIASIT?

There is no information to suggest that DIASIT affects your ability to drive a car or operate machinery.

Side effects

Like all prescription medicines, DIASIT may cause side effects. Side effects are usually mild and did not cause patients to stop taking DIASIT. The side effects reported in patients treated with DIASIT were similar to side effects in patients treated with a tablet containing no medication (a placebo)

When DIASIT is used in combination with a sulfonylurea medicine or with insulin, low blood sugar with symptoms

(hypoglycaemia) due to the sulfonylurea or insulin can occur. Lower doses of the sulfonylurea medicine or insulin may be required.

When DIASIT was used in combination with insulin, the following additional side effects were reported:

- > Flu
- > Headache

When DIASIT and metformin were started together, the following side effects were reported:

- > Diarrhoea
- > Indigestion
- > Flatulence
- > Vomiting
- > Headache

When DIASIT and pioglitazone were started together, the side effect of decreased blood sugar measurements without symptoms of hypoglycaemia was reported.

When DIASIT was used in combination with metformin and rosiglitazone, the following side effects were reported:

- > Headache
- > Low blood sugar with symptoms (hypoglycaemia)
- > Diarrhoea
- > Upper respiratory infection
- > Nausea
- > Cough
- > Fungal skin infection
- > Swelling of the hands or legs
- > Vomiting

Additional side effects have been reported in general use with DIASIT, by itself and/or with other diabetes medicines:

- > Allergic reactions, which may be serious, including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking DIASIT and call your doctor right

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away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.

- > Inflammation of the pancreas
- > Kidney problems (sometimes requiring dialysis)
- > Upper respiratory infection
- > Stuffy or runny nose and sore throat
- > Constipation
- > Vomiting
- > Headache
- > Joint pain
- > Muscle aches
- > Arm or leg pain
- > Back pain
- > Itching
- > Blisters
- > Reduced number of platelets

Tell your doctor or pharmacist if you develop any unusual side effect, or if any known side effect does not go away or gets worse.

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

How can I learn more about DIASIT and diabetes?

You may obtain further information from your doctor or pharmacist, who has more detailed information.

Storage and Disposal of DIASIT

-Storage

Store up to 30°C. Keep DIASIT and all medicines safely away from children.

-Disposal

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers

indicate the month; the last two numbers indicate the year.

Product Description

-What it looks like

DIASIT 25: Pink coloured, round shaped, biconvex, film-coating tablets, debossed with 'SG' on one side and '25' on the other side.

DIASIT 50: Light beige coloured, round shaped, biconvex, film-coated tablets, debossed with 'SG' on one side and '50' on the other side.

DIASIT 100: Beige coloured, round shaped, biconvex film-coated tablets, debossed with 'SG' on one side and '100' on the other side.

-Ingredients

- Active ingredient(s)
Sitagliptin Hydrochloride Monohydrate
- Inactive ingredient(s)
Microcrystalline cellulose, Calcium hydrogen phosphate anhydrous, Croscarmellose sodium, Sodium stearyl fumarate, Magnesium stearate, Purified water

Coating agent:
Opadry II 85F540307 Pink (for 25mg)
Opadry II 85F570116 Beige (for 50mg)
Opadry II 85F570063 Beige (for 100mg)

-MAL number

DIASIT 25: MALXXXXXXXXAZ

DIASIT 50: MALXXXXXXXXAZ

DIASIT 100: MALXXXXXXXXAZ

Manufacturer

Aurobindo Pharma Limited,
Unit-XV, Plot. No. 17A, E Bonangi Village, Parawada Mandal, Anakapalli District, Anakapalli, 531021, India

Product Registration Holder

Synerrv Sdn. Bhd.
SO-29-2, Menara 1, KL Eco City, Jalan Bangsar, Kg. Haji Abdullah Hukum, 59200 Kuala Lumpur, Malaysia

Date of revision

27/03/2024

Serial Number

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