

INSTADIP

Sitagliptin Tablets USP (25mg, 50mg, 100 mg)

What is in this leaflet

1. What INSTADIP is used for
2. How INSTADIP works
3. Before you take INSTADIP
4. How to take INSTADIP
5. While you are taking INSTADIP
6. Side Effects
7. Storage and Disposal of INSTADIP
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What INSTADIP is used for

INSTADIP contains the active substance sitagliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

How INSTADIP work

This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

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

like heart disease, kidney disease, blindness, and amputation.

Before you use INSTADIP

- When you must not use it

Do not take INSTADIP if any of the following apply to you.

- if you are allergic to Sitagliptin or any of the other ingredients of this medicine.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

- Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving INSTADIP.
- If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop INSTADIP.

Tell your doctor if you have or have had:

- a disease of the pancreas (such as pancreatitis)
- 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.
- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- joint pain
- any past or present kidney problems an allergic reaction to INSTADIP.

This medicine is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

Children and adolescents

Children and adolescents below 18 years should not use this medicine. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription including herbal medicines. This is because INSTADIP can affect the way some other medicines work. Also, some other medicines can affect the way INSTADIP works.

In particular, 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 if taking with Sitagliptin.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use INSTADIP

- How much to use

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

The usual recommended dose is:

- one 100 mg film-coated tablet
- once a day
- by mouth

If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg).

Your doctor may prescribe this medicine alone or with certain other medicines that lower blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise recommended by your doctor while taking sitagliptin.

INSTADIP can be taken with or without food.

- *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 this medicine.

- *If you stop taking INSTADIP*

Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first.

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

- *If you use too much (overdose)*

If you are taking more than the recommended dose of **INSTADIP** please contact your doctor or pharmacist

In the event of Overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you. This is so the doctor knows what you have taken.

While you are using INSTADIP

- *Things you must do*

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.

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

Ask your doctor or pharmacist for advice before taking any medicine.

- *Things you must not do*

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking **INSTADIP**, or change the dosage, without checking with your doctor.

- *Things to be careful of*

This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

Side effects

Like all medicines, **INSTADIP** can have side effects, although not everybody gets them.

Serious Side Effects

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

- Anaphylaxis (frequency not known): Sudden life-threatening allergic reaction. Symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- Angioedema (frequency not known): Serious allergic reaction characterized by swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Stevens Johnson syndrome: Severe blistering or peeling of the skin; bleeding in the lips, eyes, mouth, nose and genitals; swelling around the eyes, lips and face, rashes caused by exposure to sunlight.
- Pancreatitis: Inflammation of the pancreas. Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

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

Other side effects

Tell your doctor if you notice any of the following:

- Low blood sugar

- Headache
- Cough
- Feeling sick (nausea)
- Abdominal pain
- Diarrhea
- Indigestion
- Excessive gas in stomach or bowel
- Fungal skin infection
- Swelling of the hands or legs
- Rash

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of INSTADIP

- *Storage*

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 after "EXP". The expiry date refers to the last day of that month.

Do not store this medicine above 30°C.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. All unused **INSTADIP** tablet should be returned to the pharmacist. These measures will help protect the environment.

Product description

- *What it looks like*

25 mg

Orange, round, film-coated tablets plain on both sides

50mg

Light beige, round, film coated tablets plain on both sides

100mg

Beige, round, film coated tablets plain on both sides

Ingredients

- Active ingredient: Sitagliptin

- Inactive ingredients:

Microcrystalline cellulose, dibasic calcium phosphate (anhydrous), croscarmellose sodium, sodium stearyl fumarate, magnesium stearate, Opadry Orange 03F530010 (25mg), Opadry Beige 03F570000 (50mg), Opadry Beige 03F570001(100mg)

Packing: INSTADIP Tablet 25mg, 50mg and 100mg is available in blister of 3 x 10 tablets with Show box along with pack insert. The scored line is just for identification purpose and not meant to be halved.

MAL NO:

For 25 mg - MAL No: XXXXXXXX

For 50mg - MAL No: XXXXXXXX

For 100mg - MAL No: XXXXXXXX

**Manufacturer and product
Registration Holder**

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