

SCHEDULING STATUS

S3

SITAGLIPTIN 25 mg MEDFOUR (25 mg, film-coated tablets)

SITAGLIPTIN 50 mg MEDFOUR (50 mg, film-coated tablets)

SITAGLIPTIN 100 mg MEDFOUR (100 mg, film-coated tablets)

Sitagliptin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking SITAGLIPTIN MEDFOUR

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

1. What SITAGLIPTIN MEDFOUR is and what it is used for

SITAGLIPTIN MEDFOUR 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.

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

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.

2. What you need to know before you take SITAGLIPTIN MEDFOUR

Do not take SITAGLIPTIN MEDFOUR:

- if you are hypersensitive (allergic) to sitagliptin or to any of the other ingredients of SITAGLIPTIN MEDFOUR (listed in section 6).
- if you have a history of serious hypersensitivity reactions, such as anaphylaxis and angioedema to SITAGLIPTIN MEDFOUR or other gliptins (DPP-4).
- if you have severe liver problems.

Warnings and precautions

Take special care with SITAGLIPTIN MEDFOUR

Tell your doctor if you have or have had:

- Type 1 diabetes
- A disease of the pancreas (such as pancreatitis)

- Any past or present kidney problems
- Allergic reactions to sitagliptin

If you develop a rare skin condition that causes large, fluid-filled blisters (especially on the lower abdomen, upper thighs or armpits) you should stop taking SITAGLIPTIN MEDFOUR.

SITAGLIPTIN MEDFOUR 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 younger than 18 years should not take SITAGLIPTIN MEDFOUR.

Other medicines and SITAGLIPTIN MEDFOUR:

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

Do not take SITAGLIPTIN MEDFOUR with the following medicines:

- Ketoconazole, itraconazole (to treat fungal infections) and ritonavir (to treat viral infections) or an antibiotic called clarithromycin, particularly if you have a kidney disease or impaired kidney function. Consult your doctor, pharmacist or other healthcare provider for advice.
- 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 MEDFOUR.

SITAGLIPTIN MEDFOUR with food and drink

SITAGLIPTIN MEDFOUR can be taken with or without food.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking SITAGLIPTIN MEDFOUR.

Pregnancy

You should not take SITAGLIPTIN MEDFOUR during pregnancy.

Breastfeeding

It is not known if SITAGLIPTIN MEDFOUR passes into breast milk. You should not take SITAGLIPTIN MEDFOUR if you are breastfeeding your baby.

Driving and using machines

SITAGLIPTIN MEDFOUR may cause dizziness and drowsiness, which may affect your ability to drive or use machines.

Taking SITAGLIPTIN MEDFOUR 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.

It is not always possible to predict to what extent SITAGLIPTIN MEDFOUR may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which SITAGLIPTIN MEDFOUR affects you.

SITAGLIPTIN MEDFOUR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take SITAGLIPTIN MEDFOUR

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

Always take SITAGLIPTIN MEDFOUR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of SITAGLIPTIN MEDFOUR 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).

You can take SITAGLIPTIN MEDFOUR with or without food and drink.

Your doctor may prescribe SITAGLIPTIN MEDFOUR 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 MEDFOUR.

If you take more SITAGLIPTIN MEDFOUR than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take SITAGLIPTIN MEDFOUR

Do not take a double dose to make up for forgotten individual doses.

If you stop taking SITAGLIPTIN MEDFOUR

Take SITAGLIPTIN MEDFOUR for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

SITAGLIPTIN MEDFOUR can have side effects.

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

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

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

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

- low blood sugar levels

- 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) and bleeding in or around the pancreas
- a serious allergic skin reaction, including rash, hives, blisters on the skin/peeling skin called Stevens-Johnson syndrome

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

Tell your doctor if you notice any of the following:

Frequent

- headache

Less frequent

- easy, excessive or prolonged bleeding (thrombocytopenia)
- constipation

Unknown frequency

- interstitial lung disease
- vomiting
- an abrupt and short-lived swelling of the skin and mucous membranes
- hives
- inflamed blood vessels in the skin
- a rare skin condition causing large, fluid-filled blisters
- joint pain, muscle pain, back pain
- disease of the joints
- kidney impairment, kidney failure
- swelling of the nasal passages and the back of the throat (cold), upper respiratory tract infection

Side effects in combination with other anti-diabetic medicines

Frequent

- low blood sugar (combination with sulphonylurea and metformin)
- constipation (combination with sulphonylurea and metformin)
- influenza (with insulin (with or without metformin))
- nausea and vomiting (combination with metformin)
- flatulence (combination with metformin or pioglitazone)
- swelling in the lower limbs (combination with pioglitazone or the combination of pioglitazone and metformin)

Less frequent

- drowsiness and diarrhoea (combination with metformin)
- dry mouth (with insulin (with or without metformin))

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 SITAGLIPTIN MEDFOUR.

5. How to store SITAGLIPTIN MEDFOUR

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the tablet in the blister in the outer carton until required for use.

Do not use after the expiry date stated on the label / carton / bottle.

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 SITAGLIPTIN MEDFOUR contains

The active substance(s) is sitagliptin hydrochloride.

Each film-coated tablet contains sitagliptin hydrochloride equivalent to 25 mg, 50 mg or 100 mg sitagliptin, respectively.

The other ingredient(s) are:

Tablet core:

Calcium hydrogen phosphate, anhydrous, cellulose (microcrystalline), croscarmellose sodium, magnesium stearate and sodium stearyl fumarate

Film coating: Iron oxide yellow (E172), iron oxide red (E172), macrogol 3350, polyvinyl alcohol-part, hydrolysed, talc and titanium dioxide (E171)

What SITAGLIPTIN MEDFOUR looks like and contents of the pack

SITAGLIPTIN 25 mg MEDFOUR is round, biconvex, pink film-coated tablets. Approximate tablet dimensions 6,0 mm.

SITAGLIPTIN 50 mg MEDFOUR is round, biconvex, light beige film-coated tablets. Approximate tablet dimensions 8,0 mm.

SITAGLIPTIN 100 mg MEDFOUR is round, biconvex, beige film-coated tablets. Approximate tablet dimensions 10,0 mm.

SITAGLIPTIN 25 mg/50 mg/100 mg MEDFOUR are packed in PVC/PE/PVdC-aluminium blisters.

Medfour Healthcare CC
SITAGLIPTIN 25 mg/50 mg/100 mg MEDFOUR film-coated
tablets
Each film-coated tablet contains sitagliptin hydrochloride
equivalent to 25, 50 or 100 mg sitagliptin

Patient Information Leaflet
Date of submission: 16 July 2021
Approval: 12 July 2022

The blisters strips are packed in outer cardboard cartons with package leaflet.

Pack sizes: 14, 28, 30, 56, 60, 84, 90, 98, 180 or 196. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Medfour Healthcare CC.

31 Burger Street,

Baillie Park,

Potchefstroom

2531

+27 (0)18 290 8034/5

This leaflet was last revised in

12 July 2022

Registration number

SITAGLIPTIN 25 mg MEDFOUR: 55/21.2/0441

SITAGLIPTIN 50 mg MEDFOUR: 55/21.2/0442

SITAGLIPTIN 100 mg MEDFOUR: 55/21.2/0443