

Patient information leaflet

SITAWOK (Sitagliptin)

tablets, for oral use

Read this Patient information leaflet carefully before you start taking SITAWOK and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about SITAWOK, ask your doctor or pharmacist.

What is the most important information I should know about SITAWOK?

SITAWOK can cause serious side effects, including:

- Inflammation of the pancreas (pancreatitis) which may be severe and lead to death. Certain medical problems make you more likely to get pancreatitis.
- Before you start taking SITAWOK, tell your doctor if you have ever had:
 - a. pancreatitis
 - b. stones in your gallbladder (gallstones)
 - c. a history of alcoholism
 - d. high blood triglyceride levels
 - e. kidney problems

Stop taking SITAWOK and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

- **Heart failure:** Heart failure means your heart does not pump blood well enough.
- **Before you start taking SITAWOK,** tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor right away if you have any of the following symptoms:
 - a. increasing shortness of breath or trouble breathing, especially when you lie down
 - b. swelling or fluid retention, especially in the feet, ankles or legs
 - c. an unusually fast increase in weight
 - d. unusual tiredness

These may be symptoms of heart failure.

What is SITAWOK?

- SITAWOK is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- 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.
- SITAWOK is not for people with type 1 diabetes.
- If you have had pancreatitis (inflammation of the pancreas) in the past, it is not known if you have a higher chance of getting pancreatitis while you take SITAWOK.
- The safety and effectiveness of SITAWOK have not been established in pediatric patients.

Who should not take SITAWOK?

Do not take SITAWOK if:

- a. You are allergic to any of the ingredients in SITAWOK.
- b. See the end of this patient information leaflet for a complete list of ingredients in SITAWOK.
- c. Symptoms of a serious allergic reaction to SITAWOK may include rash, raised red patches on your skin (hives), or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.

What should I tell my doctor before taking SITAWOK?

Before you take SITAWOK, tell your doctor about all of your medical conditions, including if you:

- a. have or had inflammation of your pancreas (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

- b. kidney problems
- c. heart failure
- d. type 1 diabetes
- e. diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- f. are pregnant or plan to become pregnant. It is not known if SITAWOK will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- g. are breastfeeding or plan to breastfeed. It is not known if SITAWOK will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking SITAWOK.

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.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

Driving and using machines

- 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.

How should I take SITAWOK?

- Take SITAWOK 1 time each day exactly as your doctor tells you.
- You can take SITAWOK with or without food.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with SITAWOK.

- Your doctor may tell you to take SITAWOK along with other diabetes medicines. Low blood sugar can happen more often when SITAWOK is taken with certain other diabetes medicines.
- 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 two doses of SITAWOK at the same time.
- If you take too much SITAWOK, call your doctor right away.
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking SITAWOK.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

What are the possible side effects of SITAWOK?

SITAWOK may cause serious side effects, including:

- **Kidney problems**, sometimes requiring dialysis.
- **Low blood sugar (hypoglycemia):** If you take SITAWOK with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you use SITAWOK.

Signs and symptoms of low blood sugar may include:

- a. headache
- b. drowsiness

- c. irritability
- d. hunger
- e. dizziness
- f. confusion
- g. sweating
- h. feeling jittery
- i. weakness
- j. fast heart beat

- **Serious allergic reactions.**

If you have any symptoms of a serious allergic reaction, stop taking SITAWOK and call your doctor right away or get emergency medical help.

Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

- **Joint pain.** Some people who take medicines called DPP-4 inhibitors like SITAWOK, may develop joint pain that can be severe. Call your doctor if you have severe joint pain
- **Skin reaction.** Some people who take medicines called DPP-4 inhibitors like SITAWOK may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking SITAWOK.
- The most common side effects of SITAWOK include upper respiratory infection, stuffy or runny nose and sore throat, and headache.
- SITAWOK may have other side effects, including stomach upset and diarrhea, swelling of the hands or legs, when SITAWOK is used with metformin and rosiglitazone. Rosiglitazone is another type of diabetes medicine. Tell your doctor if you have any side effect that bothers you or does not go away.

How should I store SITAWOK?

Store SITAWOK below 30°C, protect it from moisture.

Keep SITAWOK and all medicines out of the reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away 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.

General information about the safe and effective use of SITAWOK.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet

Do not use SITAWOK for a condition for which it was not prescribed.

Do not give SITAWOK to other people, even if they have the same symptoms you have. It may harm them.

This patient information leaflet summarizes the most important information about SITAWOK. If you would like to know more information, talk with your doctor. You can ask your doctor or pharmacist for information about SITAWOK that is written for health professionals.

What are the ingredients in SITAWOK?

Active ingredient: Sitagliptin

Inactive ingredient: Ferric Oxide Yellow, Ferric Oxide Red and Titanium Dioxide

Reference:

- Prescribing information of Product