Film Coated Tablets

Sitavie

Sitagliptin+Metformin HCl

فلم کوٹڈ گولیاں

سِٹاوی

سیٹاگلپٹن +میٹ فارمن ایچ سی ایل

Composition:

Each film coated tablet contains;

Sitagliptin (as Phosphate Monohydrate U.S.P).....50mg

Metformin HCl B.P.....500mg

Reko's Specs.

Metformin belongs to a class of medicines called biguanides. They work together to control blood sugar levels in adult patients with a form of diabetes called 'type 2 diabetes mellitus'. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body. Along with diet and, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

INDICATIONS AND USAGE:

SITAVIE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Sitagliptin and Metformin is appropriate. Important Limitations of Use

SITAVIE should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

SITAVIE has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using SITAVIE

DOSAGE AND ADMINISTRATION

Recommended Dosing:

The dosage of SITAVIE should be individualized on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 50 mg sitagliptin and 500 mg metformin. Initial combination therapy or maintenance of combination therapy should be individualized and left to the discretion of the health care provider.

SITAVIE should generally be given twice daily with meals, with gradual dose escalation, to reduce the gastrointestinal (GI) side effects due to metformin

SITAVIE must not be split or divided before swallowing.

The starting dose of SITAVIE should be based on the patient's current regimen.

SITAVIE should be given twice daily with meals. The following doses are available;

Sitagliptin Phosphate Monohydrate eq. to

Sitagliptin.....50mg

Metformin HCl 500mg

The recommended starting dose in patients not currently treated with Metformin is 50 mg Sitagliptin /500 mg Metformin Hydrochloridetwice daily, with gradual dose escalation recommended to reduce gastrointestinal side effects associated with metformin.

The starting dose in patients already treated with metformin should provide Sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) and the dose of metformin already being taken. No studies have been performed specifically examining the safety and efficacy of SITAVIE in patients previously treated with other oral antihyperglycemic agents and switched to SITAVIE. Any change in therapy of type 2 diabetes should be undertaken with care and appropriate monitoring as changes in glycemic control can occur.

CONTRAINDICATIONS:

SITAVIE (Sitagliptin and metformin HCl) is contraindicated in patients with:

- Severe renal impairment (eGFR below 30 mL/min/1.73 m2)
- Hypersensitivity to metformin hydrochloride.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin.
- History of a serious hypersensitivity reaction to SITAVIE or Sitagliptin (one of the components of SITAVIE), such as anaphylaxis or angioedema.

Recommendations for Use in Renal Impairment:

Assess renal function prior to initiation of SITAVIE and periodically thereafter.

SITAVIE is contraindicated in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m2

SITAVIE is not recommended in patients with an eGFR between 30 and <45 mL/min/1.73 m2 because these patients require a lower dosage of sitagliptin than what is available in the fixed combination SITAVIE product.

WARNINGS AND PRECAUTIONS:

Lactic Acidosis

Metformin Hydrochloride

There have been postmarketing cases of metformin-associated lactic acidosis, including fatal cases. These cases had a subtle onset and were accompanied by nonspecific symptoms such as malaise, myalgias, abdominal pain, respiratory distress, or increased somnolence;

however, hypothermia, hypotension and resistant bradyarrhythmias have occurred with severe acidosis. Metformin-associated lactic acidosis was characterized by elevated blood lactate concentrations (>5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), and an increased lactate/pyruvate ratio; metformin plasma levels were generally >5 mcg/mL. Metformin decreases liver uptake of lactate increasing lactate blood levels which may increase the risk of lactic acidosis, especially in patients at risk.

If metformin-associated lactic acidosis is suspected, general supportive measures should be instituted promptly in a hospital setting, along with immediate discontinuation of SITAVIE. In SITAVIE-treated patients with a diagnosis or strong suspicion of lactic acidosis, promot hemodialysis is recommended to correct the acidosis and remove accumulated metformin (metformin hydrochloride is dialyzable, with a clearance of up to 170 mL/min under good hemodynamic conditions). Hemodialysis has often resulted in reversal of symptoms and recovery. Educate patients and their families about the symptoms of lactic acidosis and if these symptoms occur instruct them to discontinue SITAVIE and report these symptoms to their healthcare provider contains two different medicines called Sitagliptin and metformin.

Sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidylpeptidase-4 inhibitors) Metformin belongs to a class of medicines called biguanides. They work together to control blood sugar levelsin adult patients with a form of diabetes called'type 2 diabetes mellitus'. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body. Along with diet and, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

What is type 2 diabetes?
Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin thatyour 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.
Do not take Sitavie
if you are allergic to Sitagliptin or metformin orany of the other ingredients of this medicine,
if you have severely reduced kidney function.
if you have uncontrolled diabetes, with e.g severe hyperglycemia (high blood glucose),nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition inwhich substances called 'ketone bodies 'accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- If you have a severe infection or are dehydrated
- If you are going to have an X-ray where you willbe injected with a dye. You will need to stop taking Sitavie at the time of the X-ray and for 2 ormore days after as directed by your doctor, depending on how your kidneys are working.
- If you have recently had a heart attack or havesevere circulatory problems, such as 'shock' or breathing difficulties.
- If you have liver problems.
- If you drink alcohol to excess (either every day or only from time to time)
- If you are breast-feeding

Do not take Sitavie if any of the above apply to you and talk with your doctor about other ways of managing your diabetes. If you are not sure, talk to your doctor, pharmacist or nurse before taking Sitavie.

Warnings and precautions
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Sitavie If you encounter blistering of the skin it may bea sign for a condition called bullous pemphigoid.
Your doctor may ask you to stop Sitavie.
Risk of lactic acidosis Sitavie may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased withuncontrolled diabetes, serious infections, prolonged fasting or alcohol intake,

Symptoms of lactic acidosis include:
- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.
Talk to your doctor or pharmacist before taking Sitavie
- if you have or have had a disease of the pancreas (such as pancreatitis)
- if you have or have had 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
- if you have type 1 diabetes. This is sometimes called insulin-dependent diabetes

if you have or have had an allergic reaction to Sitagliptin, metformin, or Sitavie
-If you are taking a sulphonylureas or insulin, diabetes medicines, together with Sitavie, as you may experience low blood sugar levels (hypoglycemia). Your doctor may reduce the dose of your sulphonylureas or insulin.
If you need to have major surgery you must stop taking Sitavie during and for some time after theprocedure. Your doctor will decide when you must stop and when to restart your treatment with Sitavie.
During treatment with Sitavie, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/orif you have worsening kidney function.

Children and adolescents
Children and adolescents below 18 years should not use this medicine. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

Other medicines and Sitavie
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of anX-ray or scan, you must stop taking Sitavie before or at the time of the injection.

Pregnancy and breast-feeding
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. You should nottake this medicine during pregnancy or if you are breast-feeding.

Do not take Sitavie
Driving and using machinesThis medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with Sitagliptin, which may affect your ability to drive or use machines.

Precautions:
To be sold on prescription of a registered medical practitioners only.
Store at room temperature (15-30°C)
Protect from heat, light & moisture.
Keep all medicines out of the reach of children.

Presentation:
Sitavie Tablets (Sitagliptin (as Phosphate Monohydrate) + Metformin HCl) is available in Alu Alu Blister pack of 14's.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
صرف مستند ڈاکٹر کے نسخہ پر فروخت کی جائے۔
کمرے کے درجہ حرارت (15-30°C) پر رکھیں۔
دوا کو دھوپ، نمی اور روشنی سے بچائیں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
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