SITA-Met XR®

(Sitagliptin + Metformin HCl Extended Release) **Tablet**

سیٹا-میٹ ایکس آر

COMPOSITION:

SITA-Met XR 50/500 Tablet:
Each film coated tablet contains:
Sitagliptin phosphate monohydrate equivalent to
Sitagliptin USP (as Immediate release coat) ..... 50 mg.
Metformin HCl BP (as Extended release core) ..... 500 mg.

Product Specs.: BP

SITA-Met XR 50/1000 Tablet:
Each film coated tablet contains:
Sitagliptin phosphate monohydrate equivalent to
Sitagliptin USP (as Immediate release coat) ..... 50 mg.
Metformin HCl BP (as Extended release core) ..... 1000 mg.

Product Specs.: BP

SITA-Met XR 100/1000 Tablet:
Each film coated tablet contains:
Sitagliptin phosphate monohydrate equivalent to
Sitagliptin USP (as Immediate release coat) ..... 100 mg.
Metformin HCl BP (as Extended release core) ..... 1000 mg.

Product Specs.: BP

DESCRIPTION:

SITA-Met XR tablets contain two oral antidiabetic medications used in the management of type 2 diabetes:
Sitagliptin and metformin hydrochloride extended-release. SITA-Met XR consists of an extended-release metformin core tablet coated with an immediate-release layer of sitagliptin.

CLINICAL PHARMACOLOGY:

SITA-Met XR tablets combine two antihyperglycemic agents:
Sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride extended-release, a member of the biguanide class.
Pharmacokinetics: After administration of two SITA-Met XR 50 mg/1000 mg tablets once daily with the evening meal for 7 days in healthy adult subjects, steady-state for sitagliptin and metformin is reached by Day 4 and 5.

INDICATIONS & USAGE:

SITA-Met XR 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 extended-release is appropriate.
Limitations: SITA-Met XR should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. SITA-Met XR has not been studied in patients with a history of pancreatitis.

DOSAGE & ADMINSTRATION:

The dose of SITA-Met XR should be individualized on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 100 mg sitagliptin and 2000 mg metformin. In patients not currently treated with metformin, the recommended total daily starting dose of SITA-Met XR is 100 mg sitagliptin and 1000 mg metformin hydrochloride (HCl) extended-release. Patients with inadequate glycemic control on this dose of metformin can be titrated gradually, to reduce gastrointestinal side effects associated with metformin, up to the maximum recommended daily dose. In patients already treated with metformin, the recommended total daily starting dose of SITA-Met XR is 100 mg sitagliptin and the previously prescribed dose of metformin. For patients taking metformin immediate-release 850 mg twice daily or 1000 mg twice daily, the recommended starting dose of SITA-Met XR is two 50 mg sitagliptin/1000 mg metformin hydrochloride extended-release tablets taken together once daily.
SITA-Met XR should be administered with food and swallowed whole. The tablets must not be split, crushed, or chewed before swallowing.
Administration:
SITA-Met XR 100 mg sitagliptin/1000 mg metformin hydrochloride extended-release tablet should be taken as a single tablet once daily.
SITA-Met XR should be given once daily with a meal preferably in the evening.
SITA-Met XR tablets 50 mg sitagliptin/500 mg metformin hydrochloride extended-release tablets should take the two tablets together once daily (patients taking 2 tablets daily).
SITA-Met XR 50 mg sitagliptin/1000 mg metformin hydrochloride extended-release tablets) should take the two tablets together once daily (patients taking 2 tablets daily).

DOSE MODIFICATION RECOMMENDATIONS:

Use in renal impairment: Assess renal function prior to initiation of SITA-Met XR and periodically thereafter. SITA-Met XR is contraindicated in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m^2. Discontinue SITA-Met XR if the patient's eGFR later falls below 30 mL/min/1.73 m^2. Initiation of SITA-Met XR in patients with an eGFR between 30 and 45 mL/min/1.73 m^2 is not recommended. Discontinue SITA-Met XR at the time of, or prior to, an iodinated contrast imaging procedure in patients with an eGFR between 30 and 60 mL/min/1.73 m^2; in patients with a history of liver disease, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart SITA-Met XR if renal function is stable.

CONTRAINDICATIONS: Severe renal impairment (eGFR below 30 mL/min/1.73 m^2). Hypersensitivity to metformin hydrochloride. Acute or chronic metabolic acidosis, including diabetic ketoacidosis. History of a serious hypersensitivity reaction to SITA-Met XR or sitagliptin, such as anaphylaxis or angioedema.

WARNING & PRECAUTIONS: Risk of developing Lactic acidosis. Risk of acute pancreatitis. Heart failure has been observed with two other members of the DPP-4 inhibitor class. Vitamin B_{12} deficiency with Metformin. When used with an insulin secretagogue (e.g., sulfonylurea) or with insulin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia. Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Risk of serious allergic and hypersensitivity reactions in patients treated with sitagliptin, such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. History of a serious hypersensitivity reaction to SITA-Met XR or sitagliptin. Severe and disabling arthralgia has been reported in patients taking DPP-4 inhibitors. Risk of bullous pemphigoid requiring hospitalization in patients taking DPP-4 inhibitors. Risk of Acute renal failure in patients treated with sitagliptin, sometimes requiring dialysis.

DRUG INTERACTIONS:

Carbonic Anhydrase Inhibitors: Concomitant may increase the risk of lactic acidosis. Concomitant use of drugs that interfere with renal elimination of metformin could increase the risk for lactic acidosis. Alcohol is known to potentiate the effect of metformin on lactate metabolism. Co-administration with an insulin secretagogue (e.g., sulfonylurea) or insulin may require lower doses of the insulin secretagogue or insulin. Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. Patients receiving digoxin should be monitored appropriately.

SPECIFIC POPULATIONS:

Pregnancy: The limited available data with Sitagliptin/Metformin Hydrochloride XR preparation use in pregnant women are not sufficient to inform a drug-associated risk for major birth defects and miscarriage.
Lactation: There is no information regarding the presence of SITA-Met XR in human milk, the effects on the breastfed infant, or the effects on milk production.
Pediatric use: Safety and effectiveness of SITA-Met XR in pediatric patients under 18 years have not been established.
Geriatric use: Assess renal function more frequently.
Patients with renal impairment: See above.
Patients with hepatic impairment: SITA-Met XR is not recommended in patients with hepatic impairment.

ADVERSE REACTIONS: The most common adverse reactions reported are diarrhea, upper respiratory tract infection, and headache. Hypoglycemia seen with sitagliptin in combination with insulin and metformin. Other adverse effects include anaphylaxis, angioedema, rash, urticaria, cutaneous vasculitis, and exfoliative skin conditions including Stevens-Johnson syndrome, upper respiratory tract infection; hepatic enzyme elevations; acute pancreatitis, including fatal and non-fatal hemorrhagic and necrotizing pancreatitis, worsening renal function, severe and disabling arthralgia bullous pemphigoid ,constipation; vomiting; headache; myalgia; pain in extremity; back pain; pruritus; mouth ulceration; stomatitis; cholestatic, hepatocellular, and mixed hepatocellular liver injury.

OVERDOSAGE:

Sitagliptin: In the event of an overdose, it is reasonable to employ the usual supportive measures Prolonged hemodialysis may be considered if clinically appropriate. It is not known if sitagliptin is dialyzable by peritoneal dialysis. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions.

INSTRUCTIONS:

– Store below 30°C.
– Protect from heat, sunlight & moisture.
– Keep out of the reach of children.
– To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

SITA-Met XR 50/500 Tablet	:	Pack of 2 x 7 tablets.
SITA-Met XR 50/1000 Tablet	:	Pack of 2 x 7 tablets.
SITA-Met XR 100/1000 Tablet	:	Pack of 2 x 7 tablets.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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