For the use of a Registered Medical Practitioner only.

Prescribing Information

Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets

GemerSita™ IR 50/500/1 / 50/500/2 / 50/1000/1 / 50/1000/2

1. **Generic Name:** Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets

2. **Qualitative and quantitative composition**

Each Film Coated Tablet of **Gemer Sita IR 50/500/1** Contains:

Sitagliptin Phosphate Monohydrate IP	
equivalent to Sitagliptin	50 mg
Metformin Hydrochloride IP	500 mg
Glimepiride IP	1 mg
Excipients	q.s.

Each Film Coated Tablet of **Gemer Sita IR 50/500/2** Contains:

Sitagliptin Phosphate Monohydrate IP	
equivalent to Sitagliptin	50 mg
Metformin Hydrochloride IP	500 mg
Glimepiride IP	2 mg
Excipients	q.s.

Each Film Coated Tablet of **Gemer Sita IR 50/1000/1** Contains:

Sitagliptin Phosphate Monohydrate IP	
equivalent to Sitagliptin	50 mg
Metformin Hydrochloride IP	1000 mg
Glimepiride IP	1 mg
Excipients	q.s.

Each Film Coated Tablet of **Gemer Sita IR 50/1000/2** Contains:

Sitagliptin Phosphate Monohydrate IP	
equivalent to Sitagliptin	50 mg
Metformin Hydrochloride IP	1000 mg
Glimepiride IP	2 mg
Excipients	q.s.

3. **Dosage form and strength**

Tablets; (50 mg + 500 mg + 1 mg), (50 mg + 500 mg + 2 mg), (50 mg + 1000 mg + 1 mg) and (50 mg + 1000 mg + 2 mg).

4. **Clinical particulars**

4.1. Therapeutic Indications

Gemer Sita IR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

4.2. Posology and method of administration

Recommended Dosing

The usual recommended dose is one tablet twice-daily orally 15-30 minutes before meal.

Individualize the dosage of **Gemer Sita IR** on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 100 mg of sitagliptin, 2000 mg of metformin hydrochloride and 8 mg of glimepiride. Initial combination therapy or maintenance of combination therapy should be individualized and left to the discretion of the health care provider.

When colesevelam is coadministered with glimepiride, maximum plasma concentration and total exposure to glimepiride is reduced. Therefore, **Gemer Sita IR** should be administered at least 4 hours prior to colesevelam.

Elderly: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy and the higher risk of lactic acidosis. Renal function should be assessed more frequently in elderly patients.

Glimepiride is substantially excreted by the kidney. Elderly patients are more likely to have renal impairment. In addition, hypoglycemia may be difficult to recognize in the elderly. Use caution when initiating glimepiride and increasing the dose of glimepiride in this patient population.

Paediatric use: **Gemer Sita IR** is not recommended in paediatric patients.

Hepatic impairment: Use of metformin in patients with hepatic impairment has been associated with some cases of lactic acidosis. **Gemer Sita IR** is not recommended in patients with hepatic impairment.

Renal impairment: Assess renal function prior to initiation of **Gemer Sita IR** and periodically thereafter. **Gemer Sita IR** is contraindicated in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m^2. **Gemer Sita IR** is not recommended in patients with an eGFR between 30 and less than 45 mL/min/1.73 m^2 because these patients require a lower dosage of sitagliptin than what is available in the fixed combination **Gemer Sita IR** product.

Patients at increased risk for hypoglycemia (e.g., patients with renal impairment) should be started on 1 mg glimepiride once daily.

Discontinuation for Iodinated Contrast Imaging Procedures : Discontinue **Gemer Sita IR** 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 **Gemer Sita IR** if renal function is stable.

4.3. Contraindications

Gemer Sita IR is contraindicated in patients with:

- Severe renal impairment (eGFR below 30 mL/min/1.73 m^2).
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis.
- History of a serious hypersensitivity reaction to sitagliptin, or metformin, or glimepiride or any of the product's ingredients such as anaphylaxis or angioedema.
- Hypersensitivity to sulfonamide derivatives: Patients who have developed an allergic reaction to sulfonamide derivatives may develop an allergic reaction to glimepiride. Do not use glimepiride in patients who have a history of an allergic reaction to sulfonamide derivatives.

4.4. Special warnings and precautions for use

Sitagliptin Phosphate and Metformin Hydrochloride

WARNING: LACTIC ACIDOSIS

Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio, and metformin plasma levels generally >5 mcg/mL.

Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment.

If metformin-associated lactic acidosis is suspected, immediately discontinue **Gemer Sita IR** and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.

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GemerSita IR 50+500/1000+1/2 mg Tab - PI (Front/Back)
Size: 300 x 400 mm
Folding Size: 30 w x 200 mm
Market: INDIA-Pharma
SPIL/PKGDEV: AA04/Oct/2023-V01, AA05/Oct/2023-V02

SAP Code: XXXXXXX
Pharma Code: XXXXX

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