Information For the Use Empagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (extended release)

Emplozin SM 10 Tablet

Empagliflozin 10 mg + Sitagliptin 100 mg + Metformin 1000 mg Tablet Triple Therapy for Enhanced Glycemic Control in Type 2 Diabetes

Description

Empagliflozin (10 mg) + Sitagliptin (100 mg) + Metformin (1000 mg) is a combination tablet designed for the effective management of type 2 diabetes mellitus. This triple therapy combines Empagliflozin, an SGLT2 inhibitor, Sitagliptin, a DPP-4 inhibitor, and Metformin, a biguanide, each of which targets different mechanisms of glucose regulation. Together, these three medications offer comprehensive blood sugar control, reduce the risk of cardiovascular events, and promote weight loss, making this combination therapy highly effective for patients with type 2 diabetes.

Mechanism of Action

- Empagliflozin (10 mg):
 - Empagliflozin works by inhibiting the Sodium-Glucose Cotransporter 2 (SGLT2) in the kidneys, which normally reabsorbs glucose from the urine back into the bloodstream. By blocking this transporter, Empagliflozin increases glucose excretion through urine, lowering blood sugar levels. It also offers modest weight loss and can reduce blood pressure.
- Sitagliptin (100 mg):
 - Sitagliptin is a DPP-4 inhibitor that increases incretin hormone levels, which help regulate blood sugar by stimulating insulin release and inhibiting glucagon secretion. This leads to a reduction in glucose production by the liver and better insulin responsiveness, particularly after meals.

• **Metformin** (1000 mg):

Metformin is a biguanide that primarily works by reducing glucose production in the liver and improving the body's response to insulin. It also increases insulin sensitivity in muscle and fat cells, leading to more effective glucose uptake and utilization. Metformin has additional benefits, including promoting weight loss and improving lipid profiles.

Indications

Empagliflozin (10 mg) + Sitagliptin (100 mg) + Metformin (1000 mg) tablet is indicated for:

- Type 2 Diabetes Mellitus:
 - For the improvement of glycemic control in adults with type 2 diabetes, especially when diet and exercise alone are insufficient. This combination is particularly useful for patients who have not achieved adequate glucose control with monotherapy or dual therapy.

Cardiovascular Risk Reduction:

 Empagliflozin has demonstrated a reduction in the risk of cardiovascular events and death in patients with type 2 diabetes and established cardiovascular disease, making this combination beneficial for patients with high cardiovascular risk.

• Weight Management:

 The inclusion of Empagliflozin and Metformin helps with modest weight loss, which is beneficial for overweight individuals with type 2 diabetes.

Dosage and Administration

Recommended Dose:

The usual starting dose is one tablet (10 mg Empagliflozin + 100 mg Sitagliptin +

1000 mg Metformin) taken **once daily** with food to minimize gastrointestinal side effects.

Administration:

 Swallow the tablet whole with water. It is recommended to take the tablet at the same time each day to help establish a routine and improve medication adherence.

Note: Always follow the prescribed dosage and consult your healthcare provider for any adjustments based on individual needs and tolerability.

Possible Side Effects

Common Side Effects:

Gastrointestinal Symptoms:

 Nausea, diarrhea, and abdominal discomfort, particularly when starting Metformin or Sitagliptin. Taking the medication with food can help reduce these effects.

• Urinary Tract Infections (UTIs):

 Empagliflozin increases the risk of UTIs due to glucose excretion in the urine.

Increased Urination and Thirst

 Empagliflozin may cause increased urination and thirst, which can lead to dehydration if not adequately managed.

Fatigue and Respiratory Tract Infections

Serious Side Effects:

Hypoglycemia:

 While Empagliflozin alone does not generally cause low blood sugar, the combination with insulin or insulin secretagogues may increase the risk of hypoglycemia. Close monitoring of blood glucose levels is recommended.

• Ketoacidosis (DKA):

Rare cases of diabetic ketoacidosis
(DKA) have been reported with SGLT2
inhibitors like Empagliflozin. Symptoms
of DKA include nausea, vomiting,

abdominal pain, and difficulty breathing. Seek immediate medical help if these symptoms develop.

• Kidney Problems:

Empagliflozin should be used cautiously in patients with impaired renal function. Metformin should not be used in patients with severe renal impairment (eGFR < 30 mL/min/1.73m²). Regular monitoring of renal function is necessary.

• Lactic Acidosis:

 A rare but serious condition associated with Metformin is lactic acidosis, which can be fatal. Symptoms include muscle pain, difficulty breathing, dizziness, and abdominal discomfort. Seek immediate medical attention if these symptoms occur.

Pancreatitis:

 Sitagliptin has been associated with an increased risk of pancreatitis. If severe abdominal pain or vomiting occurs, discontinue the medication and consult your doctor immediately.

• Genital Infections:

 Empagliflozin increases the risk of fungal genital infections due to glucose in the urine.

Precautions

• Kidney Function:

 Empagliflozin and Metformin should be used with caution in patients with kidney problems. Empagliflozin is contraindicated in patients with severe renal impairment, and Metformin should be avoided in those with eGFR < 30 mL/min/1.73m².

• Pancreatic Disease:

 Use Sitagliptin cautiously in patients with a history of pancreatitis. If symptoms such as severe abdominal pain occur, discontinue the medication and consult your doctor.

• Diabetic Ketoacidosis (DKA):

 Although rare, DKA can occur with SGLT2 inhibitors. Be alert for symptoms of DKA, such as nausea, vomiting, and abdominal pain. Seek medical help immediately if these symptoms develop.

Alcohol:

 Metformin can increase the risk of lactic acidosis when combined with excessive alcohol consumption. Limit alcohol intake to reduce the risk of this potentially serious side effect.

• Pregnancy and Breastfeeding:

- Pregnancy: This medication is not recommended during pregnancy unless the potential benefits outweigh the risks. Consult your healthcare provider for safer alternatives during pregnancy.
- Breastfeeding: It is not known if this medication passes into breast milk.
 Discuss with your healthcare provider before using this medication while breastfeeding.

Drug Interactions

- Insulin or Insulin Secretagogues:
 - There is an increased risk of hypoglycemia when this combination is used with insulin or other insulinstimulating medications. Monitor blood glucose levels closely.
- Diuretics, ACE Inhibitors, ARBs:
 - Combining Empagliflozin with these drugs may increase the risk of dehydration and low blood pressure.
- Lithium:
 - Sitagliptin may increase the levels of lithium in the blood. Close monitoring is necessary.
- CYP3A4 Inhibitors and Rifampin:
 - Rifampin and CYP3A4 inhibitors may affect the metabolism of Sitagliptin and Empagliflozin, impacting their effectiveness. Discuss all medications with your healthcare provider.
- Storage

• Store at **room temperature** (15°C to 30°C).

- Keep the medication in a dry place, away from heat, moisture, and direct sunlight.
- Keep out of reach of children.

Disclaimer

Empagliflozin 10 mg + Sitagliptin 100 mg + Metformin 1000 mg tablet should be taken under the supervision of a healthcare provider. Always follow your doctor's instructions and consult them for any concerns or side effects. For serious side effects or emergencies, seek immediate medical assistance.

Empagliflozin 10 mg + Sitagliptin 100 mg + Metformin 1000 mg Tablet — Comprehensive Triple Therapy for Optimal Diabetes Management!

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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Panchkula-134113

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