For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing Information

DAPASER MEX® 10/500 is an extended-release preparation containing dapagliflozin 10 mg and metformin hydrochloride 500 mg**.**
DAPASER MEX® 10/1000 is an extended-release preparation containing dapagliflozin 10 mg and metformin hydrochloride 1000 mg**.**
COMPOSITION:
Each film coated bi-layered tablet contains Dapagliflozin Propanediol Monohydrate Eqv. to Dapagliflozin 10 mg and Metformin Hydrochloride IP (extended release) 500 mg.
Each film coated bi-layered tablet contains Dapagliflozin Propanediol Monohydrate Eqv. to Dapagliflozin 10 mg and Metformin Hydrochloride IP (extended release) 1000 mg.
INDICATIONS: DAPASER MEX® is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both Dapagliflozin and Metformin is appropriate.
DOSAGE AND METHOD OF ADMINISTRATION*: DAPASER MEX® should be taken once daily in the morning with food with gradual dose escalation to reduce the gastrointestinal (GI) side effects due to metformin. Physician should individualize the starting dose of DAPASER MEX® based on the patient's current treatment. Oral route. Tablet to be swallowed as whole. Do not crush, cut, or chew the tablet.
CONTRAINDICATIONS: Severe renal impairment (eGFR below 30 mL/min/1.73 m^2), end stage renal disease or patient on dialysis. History of a serious hypersensitivity reaction to dapagliflozin, such as anaphylactic reactions or angioedema, or hypersensitivity to metformin hydrochloride. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.
WARNINGS*: Lactic Acidosis: Post marketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmia. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin- associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. If lactic acidosis is suspected, discontinue DAPASER MEX® and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. **Ketoacidosis**: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue DAPASER MEX®, evaluate and treat promptly. Before initiating DAPASER MEX® , consider risk factors for ketoacidosis. Patients on DAPASER MEX® may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. **Volume Depletion**: Before initiating DAPASER MEX®, assess and correct volume status in the elderly, patients with renal impairment or low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy. **Urosepsis and Pyelonephritis**: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated. **Hypoglycemia**: In patients taking insulin or an insulin secretagogue with DAPASER MEX® , consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia. **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)**: Serious, life-threatening cases have occurred in both females and males. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment. Vitamin B12 Deficiency: Metformin may lower vitamin B12 levels. Measure hematological parameters annually. Genital Mycotic Infections: Monitor and treat if indicated.
Drug interactions*: Carbonic anhydrase inhibitors: May increase the risk of lactic acidosis. Consider more frequent monitoring. Drugs that reduce metformin clearance: May increase risk of lactic acidosis. Consider benefits and risks of concomitant use. See full prescribing information for additional drug interactions and information on interference of DAPASER MEX®with laboratory tests.
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Pregnancy*:* DAPASER MEX®is not recommended during the second and third trimesters of pregnancy. There are risks to the mother and foetus associated with poorly controlled diabetes in pregnancy.
Lactation*:* Not recommended when breastfeeding. **Geriatrics***: Higher incidence of adverse reactions related to hypotension. Assess renal function more frequently. **Renal Impairment*:** Higher incidence of adverse reactions related to volume depletion. **Hepatic Impairment***: Avoid use in patients with hepatic impairment. **Effects on ability to drive and use machines*:** Patients should be alerted to the risk of hypoglycaemia when this medicinal product is used in combination with other glucose-lowering medicinal products known to cause hypoglycaemia.
Undesirable effects*: Adverse reactions reported in >5% of patients treated with fixed dose combination of dapagliflozin and metformin were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. Adverse reactions reported in >5% of patients treated with metformin extended-release are: diarrhea and nausea/vomiting **Overdose*:** An overdose of Dapagliflozin is reasonable to employ supportive measures as dictated by the patient's clinical status. The removal of dapagliflozin by haemodialysis has not been studied. Overdose of metformin hydrochloride has occurred, including ingestion of amounts >50 grams. Lactic acidosis has been reported in approximately 32% of metformin overdose cases. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, haemodialysis may be useful for removal of accumulated drug from patients in whom metformin overdosage is suspected.

Presentation: Blister of 15 tablets

DAPASER MEX® 10/500: Aug 2023
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Source: Prescribing Information of DAPASER MEX® 10/500 and DAPASER MEX® 10/1000

***For complete information, please refer to the full prescribing information (available on request).**