For the use of a registered medical practitioner or a hospital or a laboratory only

Abbreviated Prescribing Information

Dapagliflozin/Metformin immediate-release Tablets

XigDuo® 5 mg/1000 mg

XigDuo® IR is available as a film-coated tablet for oral administration.

COMPOSITION:

XIGDUO IR is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide.

Each film-coated tablet of XIGDUO IR contains 5 mg of dapagliflozin and 1000 mg of metformin and the following inactive ingredients: hydroxypropylcellulose, microcrystalline cellulose, sodium starch glycolate, magnesium stearate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, macrogol/polyethylene glycol 3350, talc, titanium dioxide, black iron oxide, yellow iron oxide.

INDICATIONS AND USAGE-

XIGDUO IR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

XIGDUO IR is not indicated for use in patients with type 1 diabetes.
XIGDUO IR should not be used for the treatment of diabetic ketoacidosis.

DOSAGE AND ADMINISTRATION

XIGDUO IR should be taken orally, twice daily with meals to reduce the undesirable gastrointestinal effects associated with metformin.
Swallow whole, never crush, cut, or chew.
The individual components of dapagliflozin (5 mg once daily) and metformin IR (as needed) should be used when a 5 mg starting dose of dapagliflozin is considered appropriate.

For patients switching from Co-administration of dapagliflozin and metformin, XIGDUO IR should provide a total daily dose of dapagliflozin 10 mg dosed as 5 mg twice daily, plus the dose of metformin already being taken or the nearest therapeutically appropriate dose of metformin.

For patients who need a metformin dose lower than 1000 mg twice daily, the individual components of dapagliflozin and metformin should be used.

No dosage adjustment is indicated in patients with mild renal impairment.
XIGDUO IR should not be used in patients with moderate to severe renal impairment (creatinine clearance [CrCl] < 60 mL/min) or end-stage renal disease (ESRD)

DOSAGE FORMS AND STRENGTHS
5 mg dapagliflozin/1000 mg metformin HCl.

CONTRAINDICATIONS:
Moderate to severe renal impairment.
History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride.
Metabolic acidosis, including diabetic ketoacidosis.

WARNINGS AND PRECAUTIONS

Lactic acidosis: Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure Warn patients against excessive alcohol intake. If acidosis is suspected, discontinue XIGDUO IR and hospitalize the patient immediately . XIGDUO IR should generally be avoided in hepatic impairment. Ensure normal or mildly impaired renal function before initiating and at least annually thereafter. See full prescribing information.
Hypotension: Before initiating XIGDUO IR, assess volume status and correct hypovolemia in the elderly, in patients with renal impairment or low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy.
Hypoglycemia: In patients taking insulin or an insulin secretagogue with XIGDUO IR, consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia.
Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Measure hematological parameters annually. • Genital mycotic infections: Monitor and treat if indicated.
Increased LDL-C: Monitor and treat per standard of care.
Bladder Cancer: An imbalance in bladder cancers was observed in clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer.
Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with XIGDUO IR or any other antidiabetic drug.
Discontinue: Temporarily discontinue XIGDUO IR in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids.

ADVERSE REACTIONS
The most common adverse reactions associated with XIGDUO IR (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhoea, and headache.
Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhoea and nausea/vomiting.

DRUG INTERACTIONS
Cationic drugs: eliminated by renal tubular secretion may reduce metformin elimination; use with caution.

USE IN SPECIFIC POPULATIONS
Pregnancy: There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the foetus.
Nursing Mothers: Discontinue XIGDUO IR or discontinue nursing.
Geriatrics: Higher incidence of adverse reactions related to reduced intravascular volume.
Renal Impairment: Higher incidence of adverse reactions related to reduced intravascular volume and renal function.

INCOMPATIBILITIES: Not applicable. Shelf life: refer outer pack.

STORAGE: refer to outer carton.

For Further Information Contact: AstraZeneca Pharma India Limited
Block N1, 12th Floor, Manyata Embassy Business Park, Outer Ring Road, Bangalore-560045
For more information refer full prescribing information
API: Based on the India specific package insert Version 1.0, dated 14th August 2018