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

Abbreviated Prescribing Information

Dapagliflozin/Metformin extended-release Tablets

XigDuo® XR

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

COMPOSITION:

XIGDUO XR is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide in extended release form.

Dapagliflozin layer for 5 mg and 10 mg FDCs: microcrystalline cellulose, lactose anhydrous, crospovidone, silicon dioxide, and magnesium stearate.
Metformin layer for 500 mg FDCs: carboxymethylcellulose sodium, Hypromellose 2208, Hypromellose 2910, microcrystalline cellulose, silicon dioxide, and magnesium stearate.
Metformin layer for 1000 mg FDCs: carboxymethylcellulose sodium, Hypromellose 2208, silicon dioxide, and magnesium stearate.
Coating: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, FD&C yellow #6/Sunset Yellow FCF aluminum lake (5/500 only) and iron oxides for other strengths (5/1000, 10/500 and 10/1000).

INDICATIONS AND USAGE-

XIGDUO XR is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, 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 XR are not indicated for use in patients with type 1 diabetes and Diabetic ketoacidosis.

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DOSAGE AND ADMINISTRATION

Individualize the starting dose based on the patient's current treatment.
Administer once daily with evening meal.
Swallow whole, never crush, cut, or chew.
Do not exceed a daily dose of 10 mg dapagliflozin/2000 mg metformin HCl extended-release.
No dosage adjustment is indicated in patients with mild renal impairment.
XIGDUO XR 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/500 mg metformin HCl extended-release.
5 mg dapagliflozin/1000 mg metformin HCl extended-release.
10 mg dapagliflozin/500 mg metformin HCl extended-release.
10 mg dapagliflozin/1000 mg metformin HCl extended-release.

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 XR and hospitalize the patient immediately . XIGDUO XR 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 XR, 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 XR, 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 XR or any other antidiabetic drug.
Discontinue: Temporarily discontinue XIGDUO XR 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 XR (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 XR 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.
XigDuo® is a Registered Trademark of the AstraZeneca group of companies.

For Further Information Contact: AstraZeneca Pharma India Limited
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For more information refer full prescribing information
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