ORFOMAX

Orforglipron Tablet

Composition

ORFOMAX 0.8 Tablet : Each film coated tablet contains orforglipron calcium hydrate equivalent to orforglipron 0.8 mg.
ORFOMAX 2.5 Tablet : Each film coated tablet contains orforglipron calcium hydrate equivalent to orforglipron 2.5 mg.
ORFOMAX 5.5 Tablet : Each film coated tablet contains orforglipron calcium hydrate equivalent to orforglipron 5.5 mg.
ORFOMAX 9.0 Tablet : Each film coated tablet contains orforglipron calcium hydrate equivalent to orforglipron 9.0 mg.
ORFOMAX 14.5 Tablet : Each film coated tablet contains orforglipron calcium hydrate equivalent to orforglipron 14.50 mg.
ORFOMAX 17.2 Tablet : Each film coated tablet contains orforglipron calcium hydrate equivalent to orforglipron 17.20 mg.

Pharmacology

Orforglipron is an investigational, once-daily, non-peptide oral GLP-1 receptor agonist designed for the treatment of obesity and type 2 diabetes. As a small molecule, it functions as a highly potent partial agonist, stimulating insulin secretion and reducing appetite without requiring complex, non-peptide formulations. Clinical trials demonstrate significant weight loss (up to 14.7% at 36 weeks) and improved glycemic control.

Indication

Orforglipron is a GLP-1 receptor agonist indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

Dosage & Administration

Take Orforglipron orally once daily, with or without food. Swallow tablets whole. Do not break, crush, or chew. Do not take more than one tablet per day. Starting dosage is 0.8 mg once daily. After at least 30 days, increase dosage to 2.5 mg once daily. After at least 30 days on the 2.5 mg dosage, increase dosage to 5.5 mg once daily. Dosage may be increased to the next dosage level (9 mg, 14.5 mg, or 17.2 mg once daily) after at least 30 days on the current dosage, based on treatment response and tolerability. Maximum dosage is 17.2 mg once daily.

Use in Pregnancy & Lactations

Pregnancy: Weight loss offers no benefit to a pregnant patient and may cause fetal harm. When a pregnancy is recognized, advise the pregnant patient of the risk to a fetus and discontinue ORFOMAX. There are no adequate and well-controlled studies of ORFOMAX during pregnancy. Based on animal reproduction studies, there may be risks to the fetus from exposure to Orforglipron during pregnancy. Imbalances in malformations have been reported in rats and rabbits at low multiples of clinical exposure with GLP-1 receptor agonists active in those species. Orforglipron is not pharmacologically active in rats and rabbits. In animal reproduction studies, oral administration of Orforglipron to pregnant monkeys during organogenesis at doses lower than the maximum recommended human dose (MRHD) did not result in embryofetal effects. Higher dose levels and exposures could not be evaluated in monkeys due to dose limiting effects on body weight. In a rabbit dose-range finding study, oral administration of Orforglipron to pregnant rabbits during organogenesis at exposures 14 times the clinical exposure at the MRHD resulted in external malformations and decreases in fetal and placental weights in the absence of maternal toxicity (see Data). In the definitive rabbit study, oral administration of Orforglipron to pregnant rabbits during organogenesis at exposures up to 6 times the clinical exposure at the MRHD did not result in embryofetal effects. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The estimated background risk of major birth defects and miscarriage for the indicated population is increased when compared to the general population. May cause fetal harm. When pregnancy is recognized, discontinue Orforglipron.

Lactation: There are no data on the presence of Orforglipron or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Orforglipron was present in the milk of lactating rats in in vivo testing. When a drug is present in animal milk, it is likely that the drug will be present in human milk. ORFOMAX is not recommended for nursing women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ORFOMAX and any potential adverse effects on the breastfed child from ORFOMAX or from the underlying maternal condition.

Contraindications

Orforglipron is contraindicated in patients with:
• A personal or family history of MTC or in patients with MEN 2.
• Known serious hypersensitivity to Orforglipron or any of the excipients in ORFOMAX. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with GLP-1 receptor agonists.

Precautions

Risk of Thyroid C-Cell Tumors: In products with GLP-1 receptor agonist activity that are pharmacologically active in rats and mice, rodent thyroid C-cell tumors (adenomas and carcinomas) have been observed at clinically relevant exposures and are considered GLP-1 receptor-dependent effects in rodents. Orforglipron is not pharmacologically active in rats or mice and did not produce tumors in rodents. While orforglipron is pharmacologically active at the human GLP-1 receptor, the human relevance of GLP-1 receptor-dependent thyroid C-cell tumors observed in rodents has not been determined.
Acute Pancreatitis: Acute pancreatitis has been reported in patients treated with ORFOMAX. Fatal and non-fatal hemorrhagic or necrotizing pancreatitis have been observed in patients treated with GLP-1 receptor agonists. After initiation of ORFOMAX, observe patients carefully for signs and symptoms of acute pancreatitis, which may include persistent or severe abdominal pain (sometimes radiating to the back) and which may or may not be accompanied by nausea or vomiting. If pancreatitis is suspected, discontinue ORFOMAX and initiate appropriate management.
Severe Gastrointestinal Reactions: Use of ORFOMAX has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients treated with Orforglipron (approximately 3%) than patients who received placebo (1%). Severe gastrointestinal adverse reactions have also been reported postmarketing with GLP-1 receptor agonists. ORFOMAX is not recommended in patients with severe gastroparesis.
Acute Kidney Injury Due to Volume Depletion: There have been reports of acute kidney injury, in some cases requiring hemodialysis, in patients treated with GLP-1 receptor agonists or ORFOMAX. The majority of the reported events occurred in patients who experienced gastrointestinal adverse reactions leading to dehydration such as nausea, vomiting, or diarrhea. Monitor renal function in patients reporting adverse reactions to ORFOMAX that could lead to volume depletion, especially during dosage initiation and escalation of ORFOMAX.
Hypoglycemia: ORFOMAX lowers blood glucose and can cause hypoglycemia. In a trial of adults with type 2 diabetes and BMI ≥27 kg/m2 (Trial 2), hypoglycemia (plasma glucose <54 mg/dL) was reported in 2% of patients treated with Orforglipron versus 0.2% of patients receiving placebo. One patient treated with Orforglipron and no patients receiving placebo reported severe hypoglycemia in Trial 2. In Trial 2, 7% of patients treated with Orforglipron once daily in combination with sulfonylurea reported hypoglycemia compared with 0.5% of patients not taking a sulfonylurea [see Adverse Reactions. There is also increased risk of hypoglycemia in patients treated with ORFOMAX in combination with insulin. Hypoglycemia has also been associated with ORFOMAX and GLP-1 receptor agonists in adults without type 2 diabetes.
Hypersensitivity Reactions: Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists [see Adverse Reactions. If hypersensitivity reactions occur, advise the patient to promptly seek medical attention and discontinue use of ORFOMAX. ORFOMAX is contraindicated in patients with a prior serious hypersensitivity reaction to Orforglipron or to any of the excipients in ORFOMAX. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to these reactions with ORFOMAX.
Acute Gallbladder Disease: Treatment with ORFOMAX and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In a pool of two clinical trials for weight reduction (Trials 1 and 2), cholelithiasis was reported in 1% of patients treated with Orforglipron once daily and 0.7% of placebo-treated patients, and acute cholecystitis was reported in 0.4% of patients treated with Orforglipron once daily and 0.3% of placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Side Effects

Orforglipron (branded as ORFOMAX) causes primarily mild-to-moderate gastrointestinal side effects, most commonly nausea, constipation, diarrhea, and vomiting, which often occur during dose increases. Other reported effects include indigestion, stomach pain, headache, and potential hair loss. Serious, though less common, risks include thyroid tumors (based on animal studies), pancreatitis, kidney issues from dehydration, and gallbladder issues.

Storages

Store below 30°C Temperature, Protected from light and moisture. Keep all medicine out of reach of children.

Packaging

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Apex™ Pharma

Manufactured by
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