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

Gemigliptin Tartrate Sesquihydrate Tablets 50mg
Zemiglo® 50 mg

Abridged Prescribing Information

COMPOSITION
Each tablet contains gemigliptin tartrate sesquihydrate, equivalent to 50 mg gemigliptin.

THERAPEUTIC INDICATIONS
Zemiglo 50mg is a dipeptidyl peptidase-4 (dpp-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Zemiglo 50mg can be administered as monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone

DOSAGE AND ADMINISTRATION
The maximum daily recommended dose of Zemiglo is 50 mg once daily. If a dose is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day. Zemiglo can be taken with or without food.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS: Contraindicated in patients with a history of serious hypersensitivity reactions, i.e., angioedema or anaphylaxis, to another dipeptidyl peptidase-4 (DPP4) inhibitor; Type 1 diabetes or diabetic ketoacidosis

WARNINGS AND PRECAUTIONS: Renal Impairment: Zemiglo should be used with caution in patient with moderate to severe renal impairment. Zemiglo can be administered regardless of the timing of hemodialysis .Cardiac Impairment: There is limited clinical experience in patients with New York Heart Association (NYHA) Class I cardiac status. Therefore, gemigliptin should be used with caution in this population. Zemiglo is not recommended in patients with NYHA Class II-IV cardiac status. Hepatic Impairment: The influence of hepatic impairment on the pharmacokinetics of gemigliptin has not been evaluated. Cautions should be exercised during the use of Zemiglo in this population.Hypersensitive Reaction: Care should be taken when administering in patients with allergic and hypersensitive reactions to any of the ingredients in Zemiglo. Acute pancreatitis: Patients should be informed of the characteristic symptoms of acute pancreatitis: persistent, severe abdominal pain. If pancreatitis is suspected, gemigliptin should be discontinued; if acute pancreatitis is confirmed, gemigliptin should not be restarted. Caution should be exercised in patients with a history of pancreatitis. Severe and Disabling Arthralgia:There have been postmarketing reports of severe and disabling arthralgia in patients taking other DPP-4 inhibitors. The time to onset of symptoms following initiation of drug therapy varied from one day to years. Consider DPP- 4 inhibitors as a possible cause for severe joint pain and discontinue drug if appropriate.

PREGNANCY AND LACTATION: There are no adequate and well-controlled studies in pregnant women with gemigliptin; therefore, use of gemigliptin is not recommended during pregnancy. There is no information on excretion of gemigliptin into human milk. Animal studies have shown excretion of gemigliptin in breast milk. Zemiglo should not be used during breast-feeding.

ADVERSE REACTIONS:
Hypoglycaemia was reported as 1.59% in placebo controlled trials. In add-on to metformin trials, increased lipase and blood amylase of >1% was reported.

For full prescribing information please write to : Sanofi – Synthelabo (India) Private Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Updated : June 2017 Reference: Zemiglo LG SmPC V6 dated Feb-2016 – Arthralgia update – LRC dated 11-May-2017.