USE IN SPECIFIC POPULATIONS:
Pregnancy:
administered with liraglutide containing products.

Impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials,

Considerations:
defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively. Clinical
times (rat) and 10 times (rabbit) the human exposure at a dose of 0.75 U/kg/day. No adverse outcomes
including XULTOPHY ® 100/3.6 cause a delay of gastric emptying, and thereby have the potential to

Effects of Delayed Gastric Emptying on Oral Medications:

≥

less than the human exposure at the MRHD of 1.8 mg/day at all doses, based on plasma AUC. Liraglutide

umbilical hernia at 0.1 and 0.25 mg/kg/day. Pregnant rabbits given subcutaneous doses of 0.01, 0.025

controls were misshapen oropharynx and/or narrowed opening into larynx at 0.1 mg/kg/day and
during mating and the period of organogenesis, through gestation day 17 had estimated systemic

Insulin degludec was investigated in studies covering fertility, embryo-fetal development and pre- and

Intervention:
Dose adjustment and increased frequency of glucose monitoring may be required

Drugs:

Increased frequency of glucose monitoring may be required when XULTOPHY ®

Intervention:

Atypical antipsychotics (e.g., olanzapine and clozapine), corticosteroids, danazol,

Beta-blockers, clonidine, guanethidine, and reserpine

Antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents,
sulfonamide antibiotics

pramlintide, propoxyphene, salicylates, somatostatin analogs (e.g., octreotide), and

Risk Summary:  Based on animal reproduction

Drug Interactions:

XULTOPHY® 100/3.6

hypoglycemia, which may sometimes be followed by hyperglycemia.

hormones.

progestogens (e.g., in oral contraceptives), protease inhibitors, somatropin,

surgery, clonidine, and reserpine

XULTOPHY® 100/3.6. Effects have included severe nausea and severe vomiting. In the event of overdosage, appropriate

Information:

In lactating rats, insulin degludec was present in milk at a concentration lower

Concentrations approximately 50% of maternal plasma concentrations.

XULTOPHY® 100/3.6. Effects have included severe nausea and severe vomiting. In the event of overdosage, appropriate

Information:

In lactating rats, insulin degludec was present in milk at a concentration lower

Concentrations approximately 50% of maternal plasma concentrations.