# Traneta®

Linagliptin
Tablet

**Description**

Linagliptin is an orally-active inhibitor of the dipeptidyl peptidase-4 (DPP-4) enzyme which degrades the incretin hormones including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Thus, Linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon in the circulation.

**Indication and Usage**

Traneta® is indicated in the treatment of type-2 diabetes mellitus to improve glycaemic control in adults:

*As monotherapy:*

In patients inadequately controlled by diet and exercise alone and for whom Metformin is inappropriate due to intolerance, or contraindicated due to renal impairment.

*As combination therapy:*

In combination with Metformin when diet and exercise plus Metformin alone do not provide adequate glycaemic control.

In combination with a Sulphonylurea and Metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

In combination with Insulin with or without Metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.

**Dosage and Administrations**

The recommended dose of Traneta® is 5 mg once daily. Traneta® tablets can be taken with or without food.

Precautions

When used with an insulin secretagogue (e.g., sulfonylurea) or insulin, consider lowering the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

Contraindications

Traneta® is contraindicated in patients with a history of a hypersensitivity reaction to Linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity.

**Side Effects**

Side Effects reported in > 5% of patients treated with Linagliptin and more commonly than in patients treated with placebo included nasopharyngitis.

Hypoglycemia was more commonly reported in patients treated with the combination of Linagliptin and sulfonylurea compared with those treated with the combination of placebo and sulfonylurea.

Special Population

Pregnancy

Pregnancy Category B

Linagliptin has been assigned to pregnancy category B by the FDA. Animal studies have revealed evidence of fetal harm. There are no controlled data in human pregnancy. Linagliptin is only recommended for use during pregnancy when there are no alternatives and benefit outweighs risk.

*Nursing Mothers*

Available animal data have shown excretion of Linagliptin in milk at a milk-to-plasma ratio of 4:1. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Linagliptin is administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness of Linagliptin in pediatric patients under 18 years of age have not been established.

Geriatric Use

Linagliptin is minimally excreted in kidney. No overall differences in safety or effectiveness were observed between patients 65 years and over and younger patients. Therefore, no dose adjustment is recommended in the elderly population. While clinical studies of Linagliptin have not identified differences in response between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

Renal & Hepatic Impairment

No dose adjustment is recommended for patients with renal & hepatic impairment.

**Drug Interaction**

Inducers of P-glycoprotein or CYP3A4 engymes such as Rifampin decreased Linagliptin exposure, suggesting that the efficacy of Traneta® may be reduced when administered in combination with a strong P-glycoprotein or CYP3A4 inducer. Therefore, use of alternative treatments is strongly recommended when Linagliptin is to be administered with a strong P-gp or CYP3A4 inducer.

**Overdosage**

During controlled clinical trials in healthy subjects, with single doses of up to 600 mg of Linagliptin (equivalent to 120 times the recommended daily dose) there were no dose-related clinical adverse drug reactions. There is no experience with doses above 600 mg in humans.

**Pharmaceutical Precautions**

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

**Commercial Packs**

Traneta® Tablet: Box containing 10 tablets in 1X10's Alu-Alu form pack. Each film coated tablet contains Linagliptin INN 5 mg.

Manufactured by
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