

Only for the use of Medical Professionals

# Aptin®

Vildagliptin

## Description

**Aptin®** is a preparation of Vildagliptin which is a dipeptidyl peptidase-4 (DPP-4) inhibitor that lowers blood sugar levels in patients with type 2 diabetes mellitus. Vildagliptin inhibits dipeptidyl peptidase-4 (DPP-4), the enzyme responsible for the inactivation of the incretin hormones which are released into the circulation in response to food intake. Inhibition of DPP-4 results in higher levels of active incretin hormones, stimulating insulin release and decreases glucagon levels in the circulation in a glucose dependent manner. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal. These hormones are rapidly inactivated by the enzyme, DPP-4. The incretins are part of an endogenous system involved in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells by intracellular signaling pathways involving cyclic AMP. GLP-1 also lowers glucagon secretion from pancreatic alpha cells, leading to reduced hepatic glucose production by increasing and prolonging active incretin levels.

## Indications and Uses

**Aptin®** is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus in adults.

As monotherapy

- In patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with

- metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,
- a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,
- a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

As triple oral therapy in combination with

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these antidiabetic agents do not provide adequate glycaemic control.

**Aptin®** is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

## Dosage & administration

The recommended dose of **Aptin®** is

### Adults

- When used as monotherapy, in combination with metformin, in combination with thiazolidinedione, in combination with metformin and a sulphonylurea, or in combination with insulin (with or without metformin), the recommended daily dose of **Aptin®** is 100 mg, administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening.
- When used in dual combination with a sulphonylurea, the recommended dose of **Aptin®** is 50 mg once daily administered in the morning.
- When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia.

If a dose of **Aptin®** is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day.

**Children:** The safety and efficacy of vildagliptin in children and adolescents (< 18 years) have not been established.

**Note:** The safety and efficacy of vildagliptin as triple oral therapy in combination with metformin and a thiazolidinedione have not been established.

## Use in pregnancy & lactation

### Pregnancy

There are no adequate data and well controlled studies on the use of Vildagliptin in pregnant women. Studies in animals have shown reproductive toxicity at high doses. Due to lack of human data, Vildagliptin should not be used during pregnancy.

### Lactation

It is not known whether Vildagliptin is excreted in human milk. However, Vildagliptin should not be used during lactation.

## Side effects

The most common side effects of Vildagliptin are swelling of the hands, ankles or feet, dizziness, headache, trembling, hypoglycemia, nausea, constipation, burning sensation in the chest rising up to the throat (Heartburn), weight increase, itchy rash and peripheral oedema.

## Contraindications

Vildagliptin is contraindicated in patients with known hypersensitivity to Vildagliptin or to any of the excipients. It is also contraindicated in type 1 diabetes or diabetic ketoacidosis.

## Precautions

Vildagliptin is not a substitute for insulin in insulin requiring patients. Vildagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is limited experience in patients with ESRD on haemodialysis. Therefore Vildagliptin should be used with caution in patients with renal impairment. Vildagliptin should not be used in patients with hepatic impairment, including patients with pre-treatment ALT or AST > 3x ULN in hepatic impairment. Liver function should be monitored during treatment with Vildagliptin at three month intervals during the first year and periodically thereafter.

## Drug interaction

No interactions were seen with pioglitazone, metformin, glibenclamide, digoxin, warfarin, amlodipine, ramipril, valsartan or simvastatin. As with other oral antidiabetic medicinal products the glucose lowering effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics.

## Overdose

Information regarding overdose with Vildagliptin is limited. In the event of an overdose, supportive management is recommended. Vildagliptin cannot be removed by hemodialysis. However, the major hydrolysis metabolite (LAY 151) can be removed by hemodialysis.

## Pharmaceutical precautions

Store in a cool (below 25°C) & dry place. Protect from light. Keep out of the reach of children.

## Presentation

**Aptin®** tablet: Each tablet contains Vildagliptin INN 50 mg.

## Package quantities

**Aptin®** tablet: Carton of 30 tablets in blister pack.

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