Vildapin Plus™

Tablet

Vildagliptin & Metformin Hydrochloride

Description
Vildapin Plus™ combines two antihyperglycemic agents with different mechanisms of action to improve glycaemic control in patients with type 2 diabetes : Vildagliptin, a member of the DPP-4 (dipeptidyl-peptidase-4) inhibitor class and metformin hydrochloride, a member of the biguanide class.

Composition
Vildapin Plus™ 500: Each film-coated tablet contains Vildagliptin INN 50 mg & Metformin Hydrochloride BP 500 mg.
Vildapin Plus™ 850: Each film-coated tablet contains Vildagliptin INN 50 mg & Metformin Hydrochloride BP 850 mg.

Indications
Vildapin Plus™ is indicated as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus whose diabetes is not adequately controlled on metformin hydrochloride or vildagliptin alone or who are already treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets.

Dosage and Administration
The recommended starting dose of **Vildapin Plus™**should be based on the patient's current regimen of vildagliptin and/or metformin hydrochloride. In using **Vildapin Plus™** do not exceed the maximum daily dose of vildagliptin (100 mg).

Starting dose for patients inadequately controlled on metformin hydrochloride monotherapy : Based on the patient's current dose of metformin hydrochloride, **Vildapin Plus™** may be initiated at either the 50 mg/500 mg or 50 mg/850 mg tablet strength twice daily.

Starting dose for patients switching from combination therapy of Vildagliptin Plus metformin hydrochloride as separate tablets : **Vildapin Plus™** may be initiated with either the 50 mg/500 mg or 50 mg/850 mg tablet strength based on the dose of vildagliptin or metformin already being taken.
Or as directed by the physician.

Side effects
The most common side effects include tremor, headache, dizziness, low blood sugar, nausea and weakness. Patients taking vildagliptin may also experience weight gain and swelling of the legs and ankles due to excess fluid retention.

Contraindication
Contraindicated in patients with known hypersensitivity to the active substances or to any of the excipients, Diabetic Keto acidosis, Cogestive heart failure & severe renal impairment.

Precautions
Vildapin Plus™ is not a substitute for insulin in insulin-requiring patients. It should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Patients with serum creatinine levels above the normal limit should not receive **Vildapin Plus™**
Patients with renal impairment: Vildapin Plus™ should not be used in patients with renal failure or renal dysfunction.
Patients with hepatic impairment : Vildapin Plus™ is not recommended in patients with clinical or laboratory evidence of hepatic impairment
Elderly: As metformin is excreted via the kidney, and elderly patients have a tendency to decreased renal function, elderly patients taking **Vildapin Plus™** should have their renal function monitored regularly.
Paediatric patients: Safety and effectiveness of **Vildapin Plus™** in paediatric patients (below 18 years) have not been established.

Use in Pregnancy and Lactation
Pregnancy : There are no adequate and well-controlled studies in pregnant women. Therefore **Vildapin Plus™** should not be used during pregnancy unless the potential benefit justifies the potential risk to the foetus.
Lactation : As it is not known whether vildagliptin and/or metformin hydrochloride is excreted in human milk, **Vildapin Plus™** should not be administered to breast-feeding women.

Drug interaction
Vildagliptin
Vildagliptin has a low potential for drug interactions Vildagliptin is not a cytochrome P450 enzyme substrate and it dose not inhibit or induce cytochrome P450 enzymes. So it is not likely to interact with co-medications that are substrates, inhibitors or inducers of these enzymes. No clinically relevant interactions with other oral anti diabetics (Glibenclamide, Pioglitazone, Metformin), Amlodipin, Digoxin, Ramipril, Simvastatin, Valsartan or warfarin were observed after co-administration with vildagliptin.
Metformin
Metformin decreased Cmax, blood AUC of furosemide. Nifedipine increased absorption, Cmax and AUC of metformin. Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems.

Supply
Vildapin Plus™ 500: Each box contains 2x10 tablets in alu-alu blister strip.
Vildapin Plus™ 850: Each box contains 2x10 tablets in alu-alu blister strip.

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Keep all medicines out of reach of the children.
Store in a cool and dry place, protected from light.

***Further information is available on request**

Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness