Contraindications:
- Known hypersensitivity to vildagliptin or metformin hydrochloride or to any of the excipients
- Renal disease or renal dysfunction
- Congestive heart failure
- Acute or chronic metabolic acidosis including diabetic ketacidosis with or without coma
- Should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials.

Precautions/Warnings:
- Risk of lactic acidosis.
- Monitoring of renal function.
- Caution with concomitant use of medications that may affect renal function or metformin hydrochloride disposition.
- Should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials.
- Discontinue treatment in case of hypoxemia.
- Temporary discontinuation in patients undergoing surgical procedure.
- Excessive alcohol intake to be avoided.
- Not recommended in patients with hepatic impairment including patients with a pre-treatment ALT or AST >2.5 X the upper limit of normal. Liver function tests (LFT) to be performed prior to treatment initiation, at three-month intervals during the first year and periodically thereafter.

Withdrawal of therapy with Eucreas recommended if an increase in AST or ALT of 3 X upper limit normal or greater persist. Following withdrawal of treatment with Eucreas and LFT normalisation, treatment with Eucreas should not be reinitiated.
- Risk of decreased vitamin B₁₂ serum levels.
- Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Risk of hypoglycaemia.
- May be temporarily withhold in case of loss of glycaemic control.
♦ Should only be used in elderly patients with normal renal function.
♦ Not recommended in paediatric patients.

**Pregnancy:**
Should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus.

**Lactation:**
Should not be used during breast-feeding.

**Interactions:**
*Interactions with Vildagliptin:* low potential for drug interactions, no clinically relevant interactions with other oral antidiabetics (glibenclamide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin.
*Interactions with metformin hydrochloride:* furosemide, nifedipine, cationic drugs, drugs tending to produce hyperglycaemia, alcohol.

**Adverse reactions:**
**Vildagliptin:** Rare cases of angioedema. Rare cases of hepatic dysfunction (including hepatitis).

**Vildagliptin monotherapy** - Common: dizziness – Uncommon: headache, constipation, oedema peripheral.

**Metformin monotherapy** – Very common: nausea, vomiting, diarrhoea, abdominal pain, loss of appetite. Common: metallic taste. Very rare: decrease of vitamin B₁₂ absorption, lactic acidosis, liver function test abnormalities, hepatitis, skin reactions such as erythema, pruritus and urticaria.

**Other effects with combination of Vildagliptin and Metformin** - Common: headache, tremor, dizziness.

**Post-marketing experience:** - Rare: hepatitis (reversible with drug discontinuation) - Unknown: pancreatitis, urticaria.

**Packs and prices:** Country specific.

**Legal classification:** Country specific.