Prescribing Information

NovoRapid®
Insulin aspart.

NovoRapid® 10 ml vial
NovoRapid® Penfill®
NovoRapid® FlexPen®
NovoRapid® FlexTouch®
All presentations contain insulin aspart 100 U/ml.

Indication: Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

Posology and administration: Individual by subcutaneous injection. It should normally be used in combination with intermediate or long-acting insulin. NovoRapid® has a faster onset of action than soluble human insulin and should generally be given immediately before a meal. When necessary NovoRapid® can be given soon after a meal. Blood glucose monitoring and dose adjustments are recommended to achieve optimal glycaemic control. In elderly patients, patients with renal or hepatic impairment, glucose monitoring should be intensified and insulin aspart dose adjusted on an individual basis. No clinical studies in children under the age of 2 years; should only be used in this age group under careful medical supervision. Can be used in children aged 2 years and above in preference to soluble human insulin when a fast onset of action might be beneficial. Transfer from other insulin products, may require adjustment of the NovoRapid® or basal dose. May also be used in a suitable pump system for continuous subcutaneous insulin infusion, but must not be mixed with any other insulin. If necessary may be administered intravenously by healthcare professional. Penfill® designed to be used with Novo Nordisk insulin delivery systems. Penfill®, FlexPen® and FlexTouch® are designed to be used with NovoFine® and NovoTwist® needles.

Contraindications: Hypersensitivity to active substance or excipients.

Special warnings and precautions for use: Travelling between time zones may require change in the applied insulin regimen. Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and diabetic ketoacidosis, which is potentially lethal. Omission of a meal, unplanned strenuous physical exercise or too high a dose in relation to insulin requirements may lead to hypoglycaemia. Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia. Usual warning symptoms may disappear in patients with longstanding diabetes. If hypoglycaemia occurs, it may occur earlier after an injection compared with soluble human insulin. Changes in early warning symptoms of hypoglycaemia may occur on transfer between different types of insulin products. The fast onset of action should be considered in patients where a delayed absorption of food might be expected. Concomitant illness may require changes in insulin dose. Transferring to another type or brand of insulin should be done under strict medical supervision. Patients transferred to NovoRapid® from another type of insulin may require an increased number of daily injections or a change in dose. Injection site reactions, usually transitory, may occur; rotation of injection sites within an area may help reduce or prevent these reactions. Rarely injection site reactions may require discontinuation of NovoRapid®. Hypoglycaemia may constitute a risk when driving or operating machinery. NovoRapid® must not be mixed with other medicinal products except for NPH (Neutral Protamine Hagedorn) insulin and infusion fluids. Cases of cardiac failure were reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination of pioglitazone and NovoRapid® is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs**.**

Fertility, pregnancy and lactation: NovoRapid® can be used in pregnancy. Intensified blood glucose control and monitoring is recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimester. After delivery, insulin requirements normally return rapidly to pre-pregnancy values. No restrictions on use during breast-feeding. No differences in animal studies between insulin aspart and human insulin regarding fertility.

Undesirable effects: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data). Very common: Hypoglycaemia; Uncommon: Refraction disorders, diabetic retinopathy with intensification may result in temporary worsening, lipodystrophy, oedema, urticaria, rash, eruptions, injection site reactions; Rare: Peripheral neuropathy (painful neuropathy) usually reversible, may occur with rapid improvement in glycaemic control; Very rare: Anaphylactic reactions - generalised hypersensitivity reactions are potentially life-threatening. The Summary of Product Characteristics should be consulted for a full list of side effects.

MA numbers and Basic NHS Price:
1 x 10 ml vial EU/1/99/119/001 £14.08;
5 x 3 ml Penfill® EU/1/99/119/003 £28.31;
5 x 3 ml FlexPen® EU/1/99/119/009 £30.60;
5 x 3 ml FlexTouch® EU/1/99/119/020 £32.13.

Legal category: POM.

Full prescribing information can be obtained from:
Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.

Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.