

Prescribing Information

NovoMix® 30

Biphasic insulin aspart.

NovoMix® 30 Penfill®

NovoMix® 30 FlexPen®

All presentations contain soluble insulin aspart/protamine-crystallised insulin aspart 100 U/ml in the ratio 30/70.

Indication: Treatment of diabetes mellitus in adults, adolescents and children aged 10 to 17 years.

Posology and administration: Potency of insulin analogues is expressed in units (U). In patients with type 2 diabetes, NovoMix® 30 can be given in monotherapy or in combination with oral antidiabetic drugs (OADs) when blood glucose is inadequately controlled with OADs alone. The recommended starting dose is 6 U at breakfast and 6 U at the evening meal. Titration is according to pre-meal blood glucose levels (pre-breakfast glucose for adjustment of evening dose and pre-evening meal glucose for adjustment of breakfast dose). NovoMix® 30 can also be initiated once daily with 12 U at the evening meal and it is generally recommended to move to twice daily when the daily dose reaches 30 U; this can be done by splitting the dose into equal breakfast and dinner doses. If twice daily dosing results in recurrent daytime hypoglycaemic reactions the morning dose can be split into morning and lunchtime doses and thrice daily dosing instituted. Only consider combination of NovoMix® 30 with pioglitazone following clinical evaluation of the patient's risk of developing signs and symptoms of fluid related adverse reactions. Initiate NovoMix® 30 cautiously, titrating to the lowest dose required to obtain glycaemic control. In patients with type 1 diabetes the individual insulin requirement is usually between 0.5 and 1.0 U/kg/day and may be fully or partially supplied with NovoMix® 30. Dose adjustment may be necessary with increased physical activity, changes in diet or during concomitant illness. NovoMix® 30 can be used in the elderly; limited experience of NovoMix® 30 in combination with OADs in patients older than 75 yrs. Renal or hepatic impairment may reduce insulin requirements. In this population or the elderly glucose monitoring should be intensified and dose adjusted accordingly. NovoMix® 30 can be used in children and adolescents aged 10 yrs and above; limited clinical data for children aged 6-9 yrs. No studies in children under the age of 6 yrs; only use in this age group under careful medical supervision. When transferring a patient from biphasic human insulin to NovoMix® 30, start with the same dose and regimen, then titrate according to individual needs. For subcutaneous administration only; not to be used in infusion pumps. NovoMix® 30 has a faster onset of action than biphasic human insulin and should generally be given immediately before a meal. When necessary it can be given soon after a meal. Penfill® designed to be used with Novo Nordisk insulin delivery systems. Penfill® and FlexPen® are designed to be used with NovoFine® and NovoTwist® needles.

Contraindications: Hypersensitivity to active substance/excipients.

Special warnings and precautions for use: Use of inadequate doses or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. Travelling between time zones may require change in the insulin regimen. Too much insulin, omission of a meal or strenuous exercise may lead to hypoglycaemia. Compared with biphasic human insulin NovoMix® 30 may have a more pronounced glucose-lowering effect up to 6 hours after injection. This may need to be compensated for through adjustment of dose and/or food intake. Reduction of early warning symptoms of hypoglycaemia may be seen upon tightening control and symptoms may disappear with longstanding diabetes. Tighter control of glucose levels

can increase the potential for hypoglycaemic episodes and therefore require special attention during dose intensification. The fast onset of action should be considered in patients where a delayed absorption of food might be expected. Concomitant disease in kidney, liver, adrenal, pituitary or thyroid gland may require change in dose. Transferring to a new type or brand of insulin should be done under strict medical supervision; may require changes in dose/number of injections. Injection site reactions, usually transitory, may occur; rotation of injection sites may help reduce or prevent these reactions, rarely they may require discontinuation of NovoMix® 30. 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 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. Hypoglycaemia may constitute a risk when driving or operating machinery.

Fertility, pregnancy and lactation: Limited clinical experience in pregnancy. No restrictions on use during breast-feeding. No differences in animal studies between insulin aspart and human insulin regarding fertility.

Undesirable effects: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data). Very common: hypoglycaemia; Uncommon: urticaria, rash, eruptions; refraction anomalies, oedema and local hypersensitivity reactions on instituting therapy and are usually of transitory nature; diabetic retinopathy with intensification may result in temporary worsening; lipodystrophy; Rare: peripheral neuropathy – acute 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:

5 x 3 ml Penfill® EU/1/00/142/004 £28.79;

5 x 3 ml FlexPen® EU/1/00/142/009 £29.89.

Legal Category: POM.

Further 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.**

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