

5 x 3 ml

NovoMix® 30 FlexPen®

100 U/ml

Suspension for injection
in a pre-filled pen
30% soluble insulin aspart and
70% insulin aspart crystallised
with protamine

Subcutaneous use

Designed to be used with NovoFine®
or NovoTwist® disposable needles
up to a length of 8 mm

Needles are not included



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100 U/ml

Suspension for injection in a pre-filled pen.

Qualitative and quantitative composition

1 ml of the suspension contains 100 U of soluble insulin aspart*/protamine-crystallised insulin aspart* in the ratio 30/70 (equivalent to 3.5 mg).

1 pre-filled pen contains 3 ml equivalent to 300 U.

*Insulin aspart produced by recombinant DNA technology in *Saccharomyces cerevisiae*.

Pharmaceutical form: White suspension for injection in a pre-filled pen. FlexPen®.

Therapeutic indications: Treatment of patients with diabetes mellitus requiring insulin.

Posology

NovoMix® 30 dosing is individual and determined in accordance with the needs of the patient. Blood glucose monitoring and insulin dose adjustments are recommended to achieve optimal glycaemic control.

In patients with type 2 diabetes, NovoMix® 30 can be given as monotherapy. NovoMix® 30 can also be given in combination with oral antidiabetic drugs if the patient's blood glucose is inadequately controlled with oral antidiabetic drugs alone.

How to start

Insulin naïve patients: For patients with type 2 diabetes, the recommended starting dose of NovoMix® 30 is 6 U at breakfast and 6 U at dinner (evening meal). However, it can also be initiated once daily with 12 U at dinner (evening meal).

How to switch

When transferring a patient from biphasic human insulin to NovoMix® 30, start with the same dose and regimen. Then titrate according to individual needs (see *The following titration guideline*). As with all insulin products, close glucose monitoring is recommended during the transfer and in the initial weeks thereafter (see *Transfer from other insulin products*).

How to intensify

NovoMix® 30 can be intensified from once daily to twice daily.

When using NovoMix® 30 once daily, it is generally recommended to move to twice daily when reaching 30 units by splitting the dose into equal breakfast and dinner doses (50:50).

From NovoMix® 30 twice daily to thrice daily: the morning dose can be split into morning and lunchtime doses (thrice daily dosing).

How to adjust the dose

- Adjust the dose of NovoMix® 30 on the basis of the lowest pre-meal blood glucose level from the three previous days.
- Always change the mealtime dose preceding the measurement.
- Dose adjustment can be made once a week until target HbA_{1c} is reached.
- The dose should not be increased if hypoglycaemia occurred within these days.
- Adjustment of dosage may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness.

The following titration guideline is recommended for dose adjustments:

Pre-meal blood glucose level		NovoMix® 30 dose adjustment
<4.4 mmol/l	<80 mg/dl	-2 U
4.4–6.1 mmol/l	80–110 mg/dl	0
6.2–7.8 mmol/l	111–140 mg/dl	+2 U
7.9–10 mmol/l	141–180 mg/dl	+4 U
>10 mmol/l	>180 mg/dl	+6 U

Special populations

As with all insulin products, in special populations, glucose monitoring should be intensified and the insulin aspart dosage adjusted on an individual basis.

Elderly: NovoMix® 30 can be used in elderly patients; however there is limited experience with the use of NovoMix® 30 in combination with OADs in patients older than 75 years.

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