



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/62490/2026
EMA/H/C/006158

Dazparda (*insulin aspart*)

A plain-language overview of Dazparda and why it is authorised in the EU

What is Dazparda and what is it used for?

Dazparda is a medicine used to control blood glucose (sugar) levels in patients from one year of age with diabetes.

Dazparda contains the active substance insulin aspart and is a biological medicine. It is a 'biosimilar medicine'; this means that Dazparda is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Dazparda is NovoRapid. For more information on biosimilar medicines, see [here](#).

How is Dazparda used?

Dazparda can only be obtained with a prescription. It is given as an injection under the skin of the upper arm, thigh, buttock or abdomen (belly). Patients can inject themselves under the skin with Dazparda if they have been trained appropriately.

Because Dazparda is a fast-acting insulin, it is usually given just before a meal or, if more appropriate, soon after a meal. The dose of Dazparda is worked out for each patient and depends on the patient's blood glucose level.

For more information about using Dazparda, see the package leaflet or contact your doctor or pharmacist.

How does Dazparda work?

In diabetes, patients have high levels of blood glucose either because the body does not produce enough insulin, or the body is unable to use insulin effectively.

Dazparda is a replacement insulin that is very similar to the insulin made by the body.

The active substance in Dazparda, insulin aspart, is a form of insulin that acts faster than naturally produced human insulin because it is absorbed more quickly by the body. It helps control blood glucose levels, thereby improving symptoms and reducing the risk of complications of diabetes.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



What benefits of Dazparda have been shown in studies?

Laboratory studies comparing Dazparda with NovoRapid have shown that the active substance in Dazparda is highly similar to that in NovoRapid in terms of structure, purity and biological activity. Studies have also shown that giving Dazparda produces similar levels of the active substance in the body to those seen with NovoRapid.

Based on the data accumulated on biosimilars of insulin medicines, studies on the effectiveness of insulin aspart carried out with NovoRapid do not need to be repeated for Dazparda.

Studies carried out with Dazparda are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Dazparda?

The safety of Dazparda has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of NovoRapid.

For the full list of side effects and restrictions of Dazparda, see the package leaflet.

The most common side effect with Dazparda (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose).

Why is Dazparda authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Dazparda has a highly similar structure, purity and biological activity to NovoRapid and is distributed in the body in the same way.

Based on these data, and those accumulated on insulin biosimilars, Dazparda is expected to have the same effects as NovoRapid in its authorised uses.

Therefore, the Agency's view was that, as for NovoRapid, the benefits of Dazparda outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Dazparda?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dazparda have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dazparda are continuously monitored. Side effects reported with Dazparda are carefully evaluated and any necessary action taken to protect patients.

Other information about Dazparda

Dazparda received a marketing authorisation valid throughout the EU on 27 April 2026.

Further information on Dazparda, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/dazparda.

For information about the availability of this medicine in your country, contact your [national competent authority](#).

This overview was last updated in 04-2026.