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# Inpremzia (*insulin human*)

An overview of Inpremzia and why it is authorised in the EU



## What is Inpremzia and what is it used for?

Inpremzia is a medicine used to treat people with diabetes who need insulin to keep their blood glucose (sugar) level controlled. It contains the active substance insulin human.

Inpremzia is a 'biosimilar medicine'. This means that Inpremzia is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Inpremzia is Actrapid. For more information on biosimilar medicines, see here.

## How is Inpremzia used?

Inpremzia can only be obtained with a prescription. It is available as a ready-diluted solution in bags and is given as an infusion (drip) into a vein by a healthcare professional. The dose of Inpremzia depends on the patient's blood glucose level and body weight. The usual dose is between 0.3 and 1.0 international units (IU) per kilogram body weight per day. The duration of the infusion also depends on the patient's blood glucose levels, which will be monitored by a healthcare professional during the infusion. Inpremzia is not intended for long term treatment.

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

## How does Inpremzia work?

In diabetes, patients have high levels of blood glucose either because the body does not produce enough insulin to control the blood glucose or the body is unable to use insulin effectively. Inpremzia is a replacement insulin that is like the insulin made by the body.

The active substance in Inpremzia, insulin human, acts in the same way as naturally produced insulin to help glucose enter cells from the blood. By controlling the blood glucose, the symptoms and complications of diabetes are reduced.

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## What benefits of Inpremzia have been shown in studies?

Laboratory studies comparing Inpremzia with Actrapid have shown that the active substance in Inpremzia is highly similar to that in Actrapid in terms of structure, purity and biological activity. Studies have also shown that Inpremzia produces similar levels of active substance in the body to Actrapid, when given by infusion into a vein.

Because Inpremzia is a biosimilar medicine, the studies on effectiveness and safety of insulin human carried out with Actrapid do not all need to be repeated for Inpremzia.

## What are the risks associated with Inpremzia?

The safety of Inpremzia has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Actrapid.

The most common side effect with Inpremzia (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose levels) and the medicine must not be given to people whose blood glucose level is already low or suspected to be low.

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

## Why is Inpremzia authorised in the EU?

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

All these data were considered sufficient to conclude that Inpremzia will behave in the same way as Actrapid in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Actrapid, the benefits of Inpremzia 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 Inpremzia?

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

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

## Other information about Inpremzia

Inpremzia received a marketing authorisation valid throughout the EU on 25 April 2022.

Further information on Inpremzia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/inpremzia.

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