swissmedic

Summary report on authorisation dated 30 November 2024

Awiqli FlexTouch® (active substance: insulin icodec)

First authorisation in Switzerland: 7 March 2024

Solution for injection in pre-filled pen for the treatment of diabetes mellitus in adults

About the medicinal product

Awiqli FlexTouch, which contains the active substance insulin icodec, is a particularly long-acting basal insulin.[1]

Awiqli is used to treat diabetes in adults and is administered by injection.

Type 2 diabetes mellitus:
Awiqli can be used in addition to other blood glucose-lowering agents, including bolus insulin.

Type 1 diabetes mellitus:
Awiqli is injected in addition to bolus insulin.

Diabetes mellitus is a chronic disease in which blood glucose levels are elevated due to insulin deficiency or insulin resistance. Awiqli is a novel basal insulin with an exceptionally long half-life in the blood. This property allows it to be administered subcutaneously (under the skin) on a weekly basis. Treatment with Awiqli is used to control blood glucose levels. Its exceptionally long duration of action reduces the number of insulin injections required, which can also improve patient comfort.

Awiqli FlexTouch was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.
The authorisation application for Awiqli FlexTouch was submitted to the drug regulatory authorities in Australia, Canada, Singapore, and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end

[1]Basal insulins are long-acting insulins used to meet the body's background insulin needs. Insulin requirements associated with meals (food intake) are met by what are referred to as bolus insulins, which act quickly and have a short duration of action.

of the process, each authority in the Access Consortium reached a decision on the application independently.

Mode of action

Awiqli FlexTouch helps regulate blood glucose levels and works in a similar way to the body's own insulin. Once injected into the subcutaneous fat, insulin icodec slowly enters the bloodstream, where it binds strongly but reversibly to albumin, an important plasma protein. From this depot, insulin icodec is released into the bloodstream in a slow, continuous manner (slow release). The released insulin icodec binds to insulin receptors which, when activated, cause blood glucose levels to fall.

Administration

Awiqli FlexTouch, which contains the active substance insulin icodec, is a prescription-only medicine.

Awiqli is available as a clear, colourless solution in a pre-filled pen. It is injected into the subcutaneous fatty tissue once per week and should always be administered on the same day of the week.

Awiqli is available in pre-filled pens containing 700 units, 1050 units, and 2100 units of insulin icodec. The required dose is set in units. Doses between 10 and 700 units per injection can be administered in increments of 10 units. The dose to be administered is determined in consultation with the patient's doctor.

Efficacy

The efficacy of Awiqli FlexTouch was evaluated in the ONWARDS programme, which included 6 pivotal Phase 3 studies of similar design.
The results of these studies demonstrated non-inferiority of the blood glucose-lowering effect (reduction in HbA1c levels[2]) of Awiqli compared with once-daily basal insulin.

In ONWARDS 1, 2, 3, and 5, Awiqli performed better than once-daily basal insulin.

Precautions, undesirable effects, & risks

Awiqli FlexTouch must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effect (affecting more than 1 in 10 patients) of Awiqli is hypoglycaemia (low blood glucose).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

[2] HbA1c level: The HbA1c level is the long-term blood glucose level measured by the haemoglobin that binds to blood glucose in the blood. It indicates the average blood glucose level over the last 3 months as a percentage.

Why the medicinal product has been authorised

The need for an insulin that only needs to be administered once weekly is particularly evident in patients with type 2 diabetes who prefer flexible, less frequent insulin therapy. Awiqli addresses this need by providing effective glycaemic control with just 1 injection per week, which can improve patient compliance and quality of life. Despite an increased risk of hypoglycaemia (low blood glucose), Awiqli is highly effective in patients with type 2 diabetes and has acceptable risks compared to daily basal insulin.

The risk-benefit profile is also considered positive for patients with type 1 diabetes who have difficulty complying with the treatment regimen and who are thoroughly informed about the weekly pattern of hypoglycaemia risk.

The currently available data show that the benefits of treatment with Awiqli outweigh the risks. Swissmedic has therefore authorised Awiqli FlexTouch, which contains the active substance insulin icodec, for the treatment of diabetes mellitus in adults in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Awiqli FlexTouch®

Information for patients (package leaflet): Patient information Awiqli FlexTouch ®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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