



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Educational materials for healthcare professionals and patients using the diabetes medicine Awiqli

Measures intended to reduce risk of confusion with dosing requirements

Educational materials will be provided to healthcare professionals and patients expected to use the diabetes medicine Awiqli to ensure that the medicine is used correctly and to prevent medication errors such as confusion with other insulin pens.

Awiqli contains the active substance insulin icodec, a long-acting basal insulin. It is available as a solution for injection in pre-filled pens (containing 700 units of insulin icodec in 1 mL solution, 1,050 units of insulin icodec in 1.5 mL solution or 2,100 units of insulin icodec in 3 mL solution).

Awiqli is given once a week whereas other long-acting insulins are given once a day. In addition, when switching from another long-acting insulin, patients may need to take a higher dose of Awiqli to achieve faster control of blood glucose levels.

It is important that Awiqli is not used interchangeably with other insulins and that the one-time higher dose is used correctly. Dosing errors could result in patients receiving too much or too little insulin, causing hypoglycaemia (low blood glucose levels) or hyperglycaemia. Hypo- or hyperglycaemia can have serious health consequences with loss of consciousness, coma or death.

Healthcare professionals should ensure that they explain the dosing requirements to their patients and explain to them that Awiqli is for once weekly use only. Patients will receive a 'patient guide' from their healthcare professional which they should read carefully along with the package leaflet.

Information for patients and carers

- Awiqli contains insulin icodec, a long-acting basal insulin. It contains a weekly dose and is injected once a week, on the same day each week.
- Accidental daily use of Awiqli will disrupt the control of your blood sugar levels and can have serious consequences for your health.
- If you are switching to Awiqli from another long-acting insulin, your doctor will prescribe the dose that covers your weekly basal insulin need. The first once-weekly dose of Awiqli should be given on the day after the last dose of once- or twice-daily basal insulin.
- For the first injection only, your doctor may prescribe a higher dose of Awiqli. This higher dose is for the first injection only; do not use this dose for the second and following injections.



- When starting Awiqli and in the weeks after, you should measure your blood sugar levels more frequently than usual. Follow your doctor’s instructions regarding monitoring requirements and contact them if your blood sugar level seems too low or too high.
- Before starting Awiqli, you will be given a patient guide. Read this carefully together with the instructions in the package leaflet before using your medicine.
- If you have any questions about your treatment, speak to your healthcare professional.

Information for healthcare professionals

- Provide patients with the patient guide before prescribing or dispensing Awiqli.
- When switching patients from once- or twice-daily basal insulin, the recommended once-weekly Awiqli dose is the total daily basal dose multiplied by 7.
- For the first injection only, the dose can be increased for patients with type-2 diabetes for faster achievement of glycaemic control. Patients with type 1 diabetes should always receive an initial dose that is increased by 50%.
- The doses to be used are detailed in the below table:

Table 1. Awiqli dose when switching from once- or twice-daily basal insulin for type 1 and type 2 diabetes patients when a one-time higher dose is given¹

Previous total daily dose of once- or twice-daily basal insulin (units)	Recommended Awiqli once-weekly dose (units)	
	Week 1 ²	Week 2 and subsequent weeks ³
10	110	70
11	120	80
12	130	80
13	140	90
14	150	100
15	160	110
16	170	110
17	180	120
18	190	130
19	200	130
20	210	140
21	220	150
22	230	150
23	240	160
24	250	170
25	260	180

¹ All doses are rounded to the nearest 10 units.

² 1.5 x previous total daily basal insulin dose multiplied by 7. One-time higher dose given in week 1 is recommended if seeking faster achievement of glycaemic control in type 2 diabetes patients. For type 1 diabetes patients, this dose is always recommended.

³ Previous total daily basal insulin dose multiplied by 7.

Previous total daily dose of once- or twice-daily basal insulin (units)	Recommended Awiqli once-weekly dose (units)	
	Week 1 ²	Week 2 and subsequent weeks ³
26	270	180
27	280	190
28	290	200
29	300	200
30	320	210
40	420	280
50	530	350
100	1050 ⁴	700

- Explain the dosing requirements, the weekly dosing schedule and the risks that may be involved, such as the confusion with other insulins or giving a daily dose or a higher dose for longer.
- Ensure that patients and their caretakers are informed that Awiqli is given once a week only and explain how to take the first and subsequent doses.
- Tell patients to closely monitor their blood sugar levels, with instructions on how often, when starting Awiqli and in the weeks thereafter.
- Pharmacists should remind patients that Awiqli is given once a week only. Check that patients have been trained on how to use the pen and understand the weekly dosing schedule and the risks that may be involved.

More about the medicine

Awiqli is a medicine that is used for the treatment of diabetes. The active substances in Awiqli is insulin icodec.

Diabetes is a disease in which blood glucose is high, either because the body cannot produce insulin (type 1 diabetes) or because the body does not make enough insulin or cannot use it effectively (type 2 diabetes). The replacement insulin in Awiqli acts in the same way as the body's own insulin and helps glucose enter cells from the blood. This controls the level of blood glucose and reduces the symptoms and complications of diabetes. In the bloodstream, insulin icodec binds to a protein called albumin which makes it stay longer in the body, prolonging its action.

More information about Awiqli can be found on the Agency's website:

<https://www.ema.europa.eu/en/medicines/human/EPAR/awiqli>

⁴ when the required dose is larger than the maximum dose stop of the pre-filled pen (700 units), split dose with two injections may be needed.