RMP Summary

Awiqli®

(insulin icodec)

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Awiqli® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Awiqli® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Novo Nordisk Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Awiqli®.

Summary of the risk management plan for Awiqli®

This is a summary of the risk management plan (RMP) for Awiqli. The RMP details important risks of Awiqli, how these risks can be minimised, and how more information will be obtained about Awiqli's risks and uncertainties (missing information).

Awiqli's summary of product characteristics (EU PI) and its package leaflet give essential information to healthcare professionals and patients on how Awiqli should be used.

This summary of the RMP for Awiqli should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the EPAR.

Important new concerns or changes to the current ones will be included in updates of Awiqli's RMP.

I. The medicine and what it is used for

Awiqli is proposed for the treatment of diabetes mellitus in adults. It contains insulin icodec as the active substance and it is given by subcutaneous injection.

Further information about the evaluation of Awiqli's benefits can be found in Awiqli's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: EPAR link

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Awiqli, together with measures to minimise such risks and the proposed studies for learning more about Awiqli's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and EU PI addressed to patients and healthcare professionals,
- Important advice on the medicine's packaging
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly
- The medicine's legal status — the way a medicine is supplied to the public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Awiqli, these measures are supplemented with *additional risk minimisation* measures mentioned under relevant risks, below.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Awiqli are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Awiqli. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	Medication errors due to mix-up Medication errors during switch from daily basal insulin
Missing information	Pregnancy and lactation

II.B Summary of important risks and missing information

An overview of important potential risks and missing information for Awiqli is provided in the tables below.

Important potential risks	
Medication errors due to mix-up	
Evidence for linking the risk to the medicine	Medication errors are a known risk for many insulin products. Medication errors in clinical trials are systematically collected and the cases are well documented. However, clinical trials are unrepresentative of clinical practice and the appearance of the device (labelling and cartridge colour) are not the same as the marketed device.
Risk factors and risk groups	Patients with diabetes treated with basal–bolus insulin therapy (or other injectable medicine), patients with diabetes living with another person with diabetes, and visually impaired or colour-blind patients may be at a higher risk.
Risk minimisation measures	**Routine risk minimisation measures** ***Routine risk communication:*** • The risk of mix-ups is presented in Section 4.4 of the SmPC and Section 2 of the PL. ***Routine risk minimisation activities recommending specific clinical measures to address the risk:*** • Instructions for avoidance of medication errors are described in Section 4.4 of the SmPC and Section 2 of the PL • Recommendations in Section 4.4 of the SmPC and Section 3 of the PL indicates that patients with impaired vision require assistance from a person with good vision • Product appearance is described in Section 6 of the PL to prevent misidentification of medicine ***Other risk minimisation measures beyond the Product Information:*** • Product differentiation strategy to reduce misidentification; includes trade name, label text, colour branding of the carton, container label and cartridge holder. • This medicine is only available by prescription. ***Additional risk minimisation measures*** Additional risk minimisation measure in the form of patient/carer's educational guide is distributed when insulin icodec is newly launched and made available for the first 2 years to help minimise the risk of medication errors due to mix-up (see Annex 6).

	The information will describe: • Instructions to strictly adhere to weekly dosing regimen. • Instructions to always check the insulin label before each injection. • Weekly dosing frequency prominently included on the four faces of the carton.
Medication errors during switch from daily basal insulin	
Evidence for linking the risk to the medicine	For the first injection only, a one-time additional dose of insulin icodec is recommended to be utilised, during the switch to insulin icodec from daily basal insulins (and not for insulin-naïve patients). Incorrect dosing of the one-time additional dose, or following doses, can potentially result in hypoglycaemic events due to overdosing or hyperglycaemic events in the case of underdosing. Completed phase 3a studies using a device in which insulin icodec was used as the investigational drug are the evidence sources of this risk.
Risk factors and risk groups	Patients with diabetes switching from daily basal insulins to insulin icodec represent the most significant risk group. Additionally, as with all injectable insulins using pen delivery systems, patients who have vision impairments may be at a higher risk due to challenges with selecting the correct dose and may require assistance to safely use the pen-injector correctly.
Risk minimisation measures	**Routine risk minimisation measures** ***Routine risk communication:*** • The risk related to switching from daily basal insulin products is presented in Sections 4.2, 4.4, and 4.9 of the SmPC and Section 2 of the PL ***Routine risk minimisation activities recommending specific clinical measures to address the risk:*** • Instructions for switching from other daily basal insulins to insulin icodec, including a dose calculation table presenting the recommended one-time additional dose and second dose based on the daily basal insulin dosing regimen, are presented in Section 4.2 of the SmPC • Patients must be instructed to check that they inject the correct dose, especially in the first and second injection (Section 4.4 of the SmPC). It is also indicated in Section 4.2 of the SmPC and

	Section 2 of the PL that the one-time additional dose is not to be continued with subsequent doses • Patients who are uncertain about the correct dose must be instructed to consult their physician for further guidance (Section 4.4 of the SmPC) • A recommendation to only begin a switch to insulin icodec from another insulin under medical supervision is included in Section 4.4. of the SmPC and Section 2 of the PL • In Section 3 of the PL, switching to insulin icodec is discussed with specific mention that a doctor should prescribe you the first and second dose, and that subsequent doses should be determined in consultation with a doctor • In Section 4.9 of the SmPC, specific warning is included concerning the risk for overdose if the one-time additional dose continues to be taken with subsequent dosing. • Recommendations in Section 4.4 of the SmPC and Section 3 of the PL indicates that patients with impaired vision require assistance from a person with good vision ***Other risk minimisation measures beyond the Product Information:*** • This medicine is only available by prescription ***Additional risk minimisation measures*** Additional risk minimisation measure in the form of patient/carer's educational guide is distributed when insulin icodec is newly launched and made available for the first 2 years to help minimise the risk of medication errors during switch from other basal insulin (see Annex 6). The information will describe: • Information on use of one-time additional dose during initiation. • Key differences between first dose and second dose. • Cautionary text on the carton "The pen shows the dose, One step equals 10 units".

Abbreviations: EU PI = European Union product information ; PL = product leaflet ; SmPC = Summary of Product Characteristics.

Missing information	
Pregnancy and breast-feeding	
Risk minimisation measures	***Routine risk communication:*** • Lack of experience in this population is mentioned in Section 4.6 of the SmPC (Fertility, pregnancy and lactation). • It is acknowledged that, as a result of potential exposure during breast-feeding, a risk to the newborns/infants cannot be excluded (Section 4.6, SmPC) ***Routine risk minimisation activities recommending specific clinical measures to address the risk:*** • In Section 2 of the PL, patients are encouraged to discuss with a doctor, nurse or pharmacist whether to begin therapy with insulin icodec while pregnant or breast feeding. • It is also advised that a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from insulin icodec therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman (Section 4.6, SmPC). ***Other risk minimisation measures beyond the Product Information:*** • This medicine is only available by prescription.

Abbreviations: EU PI = European Union product information ; PL = product leaflet ; SmPC = Summary of Product Characteristics.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Awiqli.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Awiqli.