Summary of Risk Management Plan for Baqsimi (Glucagon)

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

Baqsimi's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Baqsimi should be used.

This summary of the RMP for Baqsimi should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR)].

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

I - The Medicine and What It is Used for

Baqsimi is authorised for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 4 years and over with diabetes mellitus (see SmPC for the full indication). It contains glucagon as the active substance, and it is given by nasal dosing device.

Further information about the evaluation of Baqsimi's benefits can be found in Baqsimi's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage.

https://www.ema.europa.eu/en/medicines/human/EPAR/baqsimi

II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Baqsimi, together with measures to minimise risks about Baqsimi, 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 SmPC addressed to patients and healthcare professionals;
- important advice on the medicine's packaging.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report assessment, 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 Baqsimi 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 Baqsimi. 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	Inappropriate use of the device leading to loss of drug benefit
Missing information	None

II.B Summary of Important Risks

Important potential risk: Inappropriate use of the device leading to loss of drug benefit	
Evidence for linking the risk to the medicine	In an emergency setting, the first-time user who is not familiar with the device or its instructions for use may fail to administer the medication correctly to the patient.
Risk factors and risk groups	Risk groups for inappropriate use of the device are likely to be first-time users who are unfamiliar with the device and the instructions for use.
Risk minimisation measures	Routine risk minimisation measures: Instructions for proper use of glucagon—SmPC Sections 4.2 (Posology and method of administration) and 6.6 (Special precautions for disposal and other handling), PL Section 3 (How Baqsimi is to be given), IFU (Important points to know and preparing the dose), device carton (Do not press the plunger prior to insertion as you will lose the dose), and tube container (Do not press plunger before insertion).. Instructions for patients to discuss the proper use of glucagon with family and friends before it is needed—PL Section 2 (What you need to know before you receive Baqsimi) and IFU (Initial statement). Instructions for users to call for medical help right away after administering glucagon—SmPC Section 4.2 (Posology and method of administration), PL Section 3 (How Baqsimi is to be given), and IFU (After giving the dose). Additional risk minimisation measures: • Administration leaflet • Online instructional video • Demonstration kit that includes a trainer device with an administration leaflet unique to the trainer device

Abbreviations: IFU = Instructions for Use; PL = package leaflet; SmPC = Summary of Product Characteristics.

II.C Post-authorisation Development Plan

II.C.1 Studies That Are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Baqsimi.

II.C.2 Other Studies in Post-authorisation Development Plan

There are no studies required for Baqsimi.