Summary of the risk management plan

This is a summary of the RMP for Kinpeygo. The RMP describes important risks of Kinpeygo and uncertainties (missing information).

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

This summary of the RMP for Kinpeygo 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 European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Kinpeygo is a new treatment that has been developed by Calliditas Therapeutics AB to specifically target the disease mechanisms of primary immunoglobulin A (IgA) nephropathy (IgAN). Kinpeygo is an oral, modified release hard capsule formulation of the glucocorticosteroid budesonide which combines a delayed capsule disintegration with a prolonged release of the active substance budesonide in the ileum. By directing the release of budesonide to the ileum, where Peyer's patches reside in high density, a local pharmacological effect is anticipated.

Kinpeygo is indicated for the treatment of primary IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

For further information, refer to https://www.ema.europa.eu/en/medicines/human/EPAR/kinpeygo

II. Risk associated with the medicine and activities to minimize or further characterize the risks

Important risks of Kinpeygo, together with measures to minimise such risks and the proposed studies for learning more about Kinpeygo'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 SmPC 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 patient (e.g., with or without prescription) can help to minimise its risks.

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 Reports (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important and missing information

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• Use in pregnancy and lactation

II.B Summary of important risks

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• Use in pregnancy and lactation
Risk minimization measures	Routine risk minimisation measures: – SmPC section 4.6, 5.3 – Legal status: Prescription only medicinal product Additional risk minimisation measures: – None

II.C Post-authorisation development plan

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

The following studies are conditions of the marketing authorization:

Study/ Status	Summary of objectives	Efficacy uncertainties addressed	Milestones	Due Date
Efficacy studies which are Specific Obligations in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances				
Pivotal Phase 3 Clinical Study NefIgArd (NEF-301) Efficacy and Safety of Nefecon* in Patients With Primary IgAN Study Part B: 12-	This is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, and tolerability of oral Nefecon* compared to matching placebo in patients with primary IgAN on a	Long-term efficacy (difference in eGFR over 2-year period)	Last Patient In (LPI)	21/01/2021
			Last Patient Last Visit (LPLV)	Q1/2023

Study/ Status	Summary of objectives	Efficacy uncertainties addressed	Milestones	Due Date
month observational follow up period Status: ongoing *(Note: Part A of NeflgArd Study serves as basis for conditional marketing authorisation application)*	background of optimized RAS inhibitor therapy. The study consists of 2 parts, Part A and Part B. Results from Part A are used for the marketing authorisation application (conditional approval). Part B of the study consists of a 12-month observational Follow up Period; no study drug will be administered during Part B. Part A and B will be blinded. Safety will be monitored by an independent Data Safety Monitoring Board.		Final Study Report	Q2/2023

*Kinpeygo is referred to as “Nefecon” in clinical studies

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

There are no other studies required for Kinpeygo.