Macrogol 3350 + Sodium Chloride +
Potassium Chloride + Sodium Hydrogen Carbonate
13.125 g + 351 mg + 47 mg + 179 mg
Powder for Oral Solution

Part VI: Summary of activities in the risk management plan by product

Part VI.1 Elements for summary tables in the EPAR

Table 6-1 Part VI.1.1 Summary table of safety concerns

Important identified risks	Fluid-electrolyte imbalance
	Hypersensitivity reactions including anaphylaxis
	Risk in patients with glucose-galactose malabsorption
Important potential risks	Potential to alter absorption and efficacy of other medicinal products
Missing information	Use during pregnancy and lactation

Table 6-2 Part VI.1.2 Table of on-going and planned additional PhV studies/activities in the Pharmacovigilance Plan

None

Table 6-3 Part VI.1.3 Summary of Post authorisation efficacy development plan

None

Table 6-4 Part VI.1.4 Summary table of risk minimisation measures

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
Fluid-electrolyte imbalance	Guidance is given in section 4.4 “Special warnings and special precautions for use” of the SmPC.	None
Hypersensitivity reactions including anaphylaxis	Guidance is given in sections 4.4 “Special warnings and special precautions for use” and 4.8 “Undesirable effects” of the SmPC.	None
Risk in patients with gluocose-galactose malabsorption	Guidance is given in sections 4.4 “Special warnings and special precautions for use” and 6.1 “List of excipients” of the SmPC.	None
Potential to alter absorption and efficacy of other medicinal products	Guidance is given in section 4.5 “Interaction with other medicinal products and other forms of interaction” of the SmPC.	None

Use during pregnancy and lactation	Guidance is given in section section 4.6 “Pregnancy and lactation” of the SmPC.	None

Part VI.2 Elements for a Public Summary

Part VI.2.1 Overview of disease epidemiology

Constipation is a very common condition worldwide both in adults and children. It impacts the physical and emotional well-being considerably. The frequency of constipation differs from 2.5% to 79% in adults and from 0.7% to 29.6% in children. It seems that constipation becomes slowly more frequent after the age of 60 years. Females have more often constipation. In general, in Asia constipation is present more often (average 10.8%), compared to North America (16%), Europe (19.2%) and islands of the tropical Pacific Ocean (19.7%). People with lower income have considerably more frequently constipation than wealthier ones. Constipation occurs less frequently in people with more years of (parental) education and more frequently in people with high body mass index and immobility or less physical activity. Further risk factors for constipation are low-fibre food, living in a highly densely populated community, constipation in the family and experiencing anxiety, stressful life events and depression. [1)]

Part VI.2.2 Summary of treatment benefits

Macrogol is a safe and effective treatment for constipation, even in children and elderly patients. Due to higher water content, it increases the volume of the faecal mass, which in turn triggers forceful bowel movements, via distension of the colonic wall. The increased water content softens the faeces and eases motion. A relatively low dose of Macrogol improves stool frequency and consistency in patients with chronic constipation. Macrogol continues to be effective in the long term without necessitating dose increase over time. It is usually not associated with severe side effects. Diarrhoea and bloating may be experienced which can be alleviated by taking Macrogol before going to bed. Macrogol does not alter the normal structure of the gastrointestinal mucosa (surface of the bowel). [2)]

Part VI.2.3 Unknowns relating to treatment benefits

None.

Part VI.2.4 Summary of safety concerns

Table 6-5 Important identified risks

Risk	What is known	Preventability
Change in body’s fluid or salts levels (Fluid-electrolyte imbalance)	Signs of a change in body’s fluid or salts levels can be swelling (mainly in the ankles), feeling weak, increasingly tired or increased thirst with headache.	If you experience any of these side effects, stop taking Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate,and see your doctor immediately. .
Allergy (Hypersensitivity reactions including anaphylaxis)	The orange flavour and the lemon lime flavour contain sulphur dioxide (E220), which may rarely cause severe allergic reactions	Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate should be avoided in patients

Risk	What is known	Preventability
	and bronchospasm (a sudden shortness of breath or wheezing). Other symptoms of allergic reactions include rash, itching, shortness of breath or difficulty in breathing.	with a known history of allergy to its active or other ingredients. If a patient experiences any of the mentioned side effects, this medicinal product should be stopped and the doctor visited immediately.
Risks in patients with intolerance to some sugars (Risk in patients with gluocose-galactose malabsorption)	The orange flavour in Macrogol 3350 contains glucose.	If a patient has been told by his doctor that he has an intolerance to some sugars, the doctor should be contacted before this medicinal product is taken.

Table 6-6 Important potential risks

Risk	What is known
Potential of lower effect of other medicinal products, e.g. anti-epileptics (Potential to alter absorption and efficacy of other medicinal products)	Macrogol 3350 raises the solubility of medicinal products, e.g. anti-epileptics, which are soluble in alcohol and relatively insoluble in water. It is a theoretical possibility that absorption of these drugs could be reduced transiently. Such medicinal products may not work as effectively during use with Macrogol 3350.

Table 6-7 Missing information

Risk	What is known
Use during pregnancy and lactation	There is no experience with the use of Macrogol 3350 during pregnancy and lactation and it should only be used if considered absolutely necessary by the physician.

Part VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other Health Care Professionals (HCPs) with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

Part VI.2.6 Planned post authorisation development plan

None

Part VI.2.7 Summary of changes to the Risk Management Plan over time

N/A. This is the first Risk Management Plan.