Movicol® Pediatric Plain

25.9.2015, Version 3.1

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Constipation
Approximately one quarter of the general population is affected by chronic constipation; women are more likely to experience constipation than men. In children, chronic constipation is common with approximately 5-30% experiencing this problem.

Constipation often occurs due to factors such as disease processes including neurological conditions and diabetes, adverse effects of medication and dietary and exercise patterns. In children a mixture of genetic disposition, low socioeconomic status, inadequate daily fibre and fluid intake and immobility are related to the development of chronic constipation. In many children constipation is triggered by experiencing painful bowel movements.

Faecal impaction

Please note that information on faecal impaction is included for completeness as the product is not licensed for use in faecal impaction in all countries.

Approximately 30% of older people in institutional care suffer from faecal impaction. It is particularly common in people with dementia and those who have problems with mobility.

Approximately 30 to 75% of children with long-standing constipation also have faecal impaction and/or rectal faecal impaction. The condition is more common in children with a genetic predisposition, low socioeconomic status, inadequate daily fibre and fluid intake and immobility. Those children who develop withholding behaviour (try to 'hold it in') after experiencing a painful or frightening bowel evacuation may go on to suffer faecal impaction.

VI.2.2 Summary of treatment benefits

The efficacy of MOVICOL®, for the treatment of constipation, has been studied in 22 clinical trials (3 of which were studies in children), including approximately 3000 treated patients. These clinical trials examined the effect of MOVICOL® on constipated patients. They confirmed that treatment with MOVICOL® relieved constipation enabling patients to open their bowels comfortably.

The efficacy of MOVICOL® for the treatment of faecal impaction has been studied in in 6 clinical trials (2 of which were paediatric studies) involving over 200 patients. The clinical trials examined the effectiveness of MOVICOL® in 'unblocking' patients who were so severely constipated that they were unable to open their bowels at all but sometimes soil (leak faeces) instead. The clinical trials showed that MOVICOL® was effective in 'unblocking' these patients**.**

VI.2.3 Unknowns relating to treatment benefits

Following an extensive clinical trials programme, MOVICOL® has now been approved by the medicines regulatory authorities for use in patients in 42 countries. The product has been used widely over the past 19 years and has been found to be effective and well tolerated by patients seeking relief from constipation and faecal impaction.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Severe allergic reaction (anaphylaxis)	Very rarely serious allergic reactions have been reported with the use of MOVICOL®. The majority of patients who experience an allergic reaction make a full recovery although they may need medical treatment.	MOVICOL® should not be prescribed to patients with known hypersensitivity to the active substance or its excipients.
Changes in the levels of blood chemicals (fluid/electrolyte shifts)	Disturbances in the blood levels of sodium and potassium ("electrolytes") have been reported. Sodium and potassium are needed to control blood pressure and the amount of water in the cells of the body and for the normal activity of muscles and cells. . Low levels of these blood chemicals can cause a variety of symptoms which could include headaches, confusion, nausea and vomiting, weakness, fatigue, constipation, and muscle cramping.	If any symptoms occur, treatment should be discontinued immediately, electrolyte levels measured, and corrective action taken as appropriate.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)

Drug interactions	As with any laxative or other factor which might increase bowel transit time, there may be a potential for reduced absorption, concentration and effectiveness of some medications when taken at the same time as MOVICOL®.
Dehydration	It is possible that patients may not realise that they need to continue to drink normally whilst taking MOVICOL® which does not replace the fluid they would normally drink.

Missing information

Risk	What is known
Use in Pregnancy and Lactation	No clinical trials have been undertaken using MOVICOL® in pregnant or breast feeding women. MOVICOL® is virtually unabsorbed into the body and so no adverse effects are expected if a pregnant or breast feeding woman uses the product. In view of these facts and the history of safe use, the product has been authorised by medicines regulatory authorities for use in Pregnancy and Lactation. Naturally, Norgine will continue to monitor any reports of use in pregnancy and lactation.

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 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. The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None required.

Studies which are a condition of the marketing authorisation

No studies are required

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

Version 2.0 was the first Risk Management Plan submitted in this format.

Version 3.0 created to include the addition of MOVICOL® Ready to Take