# PART VI SUMMARY OF THE RMP

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|---|---|
| Active substance | Sodium picosulphate |
| Product concerned | Laxoberal |
| Name of MAH or applicant | Boehringer Ingelheim International GmbH |
| DLP for this module | 28 Feb 2015 |
| Version number of RMP when this module was last updated | 1.0 |

# PART VI.1 ELEMENTS FOR SUMMARY TABLES IN THE EPAR

PVI.Table 1 Summary of the safety concerns

| | |
|---|---|
| Important identified risks | Syncope |
| Missing information | Use in pregnancy |

PVI.Table 2 Table of ongoing and planned additional PV studies/activities in the PV plan

| Study/activity[1] | Objectives | Safety concerns addressed | Status[2] | Date for submission of interim or final reports[3] |
|---|---|---|---|---|
| None | | | | |

[1] Type, title and category (1-3).
[2] Planned or started.
[3] Planned or actual.

PVI.Table 3 Summary of post-authorisation efficacy development plan

| Study (type and study number) | Objectives | Efficacy uncertainties addressed | Status (planned/started) | Date for submission of interim or final reports |
|---|---|---|---|---|
| None | | | | |

PVI.Table 4 Summary of risk minimisation measures

| **Safety concern** | **Routine risk minimisation measures** | **Additional risk minimisation measures** |
|---|---|---|
| *Important identified risks* | | |
| Syncope | Product information | None |
| *Missing information* | | |
| Use in pregnancy | Product information | None |

# PART VI.2 ELEMENTS FOR A PUBLIC SUMMARY

## Part VI.2.1 Overview of disease epidemiology

Constipation is a common problem that has been estimated to affect up to one person in every three in Europe, at least occasionally, although estimates vary. It is more frequent in the

elderly, women and during pregnancy. Many factors can contribute to developing constipation, including: lack of fibre, fluids or exercise, as well as some medical conditions and taking certain medicines [P08-13256; P13-05726; R08-2188; R11-0961].

Constipation symptoms are usually mild, but in some patients can become severe. Complications can arise, often due to straining, which may be painful and difficult to treat.

Initially, the treatment of constipation usually involves advice on eating more fibre, drinking enough fluid, and exercising, although evidence that these lifestyle changes have a meaningful impact on constipation is limited. In those cases, several types of medicine are available, including: laxatives that soften stools, increase stool size, or help stools move through the bowels [P13-05726].

### Part VI.2.2 Summary of treatment benefits

One main study measured the average number of complete bowel movements in 367 constipated patients during a 4-week period. They were treated once daily with either oral drops of sodium picosulphate or a dummy drug (placebo). The average number of complete spontaneous bowel movements significantly increased by 2.5 per week in the group taking sodium picosulphate, compared with an increase of 0.6 per week in the group taking dummy drug. Sodium picosulphate-treated patients had an initial bowel movement more quickly after treatment started, and had greater improvements in their everyday functioning and well-being, compared with dummy drug-treated patients [P10-03187].

Another study compared how often 57 constipated patients passed stools and strained on the toilet when treated once daily with oral sodium picosulphate or a dummy drug. Patients taking sodium picosulphate had a significantly better response than those taking dummy drug, passing more stools over a week and straining on the toilet less [P07-07478].

A study in 144 constipated patients showed that sodium picosulphate was as effective as another medicine called bisacodyl (which is converted to the same active incredient as Laxoberal in the body) in increasing the number of bowel movements and softening stools during a four-week period. Other studies have supported the effectiveness of sodium picosulphate in treating constipation [P07-03176].

### Part VI.2.3 Unknowns relating to treatment benefits

The studies covered a wide selection of patients with constipation including children, the elderly, and pregnant and lactating women. Although most patients were white Caucasians, sodium picosulphate has been used worldwide for several decades and there is no evidence that it is less effective for other racial groups.

## Part VI.2.4 Summary of safety concerns

PVI.Table 5 Important identified risks

| Risk | What is known | Preventability |
|---|---|---|
| Fainting (Syncope) | No fainting has been reported in patient studies associated with the use of sodium picosulphate.<br>Fainting in association with Laxoberal use has been reported in patients outside of clinical studies.<br>Some patients react to abdominal spasms or passing stools with fainting. The details available for these cases suggest that these fainting events might be caused by passing stool or straining at stool, or an abnormal response to severe abdominal pain. These reactions may be related to the constipation, and not necessarily to the use of sodium picosulphate. | Dizziness may be a first sign of fainting. Knowing that dizziness and/or fainting due to an abnormal reaction to abdominal spasm or defaecation may occur, patients should avoid potentially hazardous tasks or act with caution when feeling dizzy or experiencing abdominal cramps as described in several sections of the prescribing information and the patient information leaflet. |

PVI.Table 6 Missing information

| Risk | What is known |
|---|---|
| Use in pregnancy | There are no adequate and well-controlled studies in pregnant women. Lengthy experience, however, has shown no evidence of undesirable or damaging effects during pregnancy. |

## Part VI.2.5 Summary of additional 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 (PL). The measures in these documents are known as routine risk minimisation measures.

The SmPC and the PL for Laxoberal can be found on the national directories of the responsible Health Authorities in the EU Member States where Laxoberal is registered. As this medicinal product is registered through national authorisation procedures, no European Public Assessment Report (EPAR) is available.

This medicine has no additional risk minimisation measures.

## Part VI.2.6 Planned post-authorisation development plan

No studies are planned, as this medicine is already well characterised and has been available for many years.

### Part VI.2.7 Summary of changes to the RMP over time

There have been no changes to the RMP over time, as this is the first version.

## PART VI.3 ABBREVIATIONS

| | |
|---|---|
| DLP | Data lock point |
| EPAR | European public assessment report |
| MAH | Marketing authorisation holder |
| PL | Package leaflet |
| RMP | Risk management plan |
| SmPC | Summary of product characteristics |

## PART VI.4 REFERENCES

### Part VI.4.1 Published references

P07-03176 Kienzle-Horn S, Vix JM, Schuijt C, Peil H, Jordan CC, Kamm MA, Comparison of bisacodyl and sodium picosulphate in the treatment of chronic constipation. Curr Med Res Opin 23 (4), 691 - 699 (2007).

P07-07478 Wulkow R, Vix JM, Schuijt C, Peil H, Kamm MA, Jordan C, Randomised, placebo-controlled, double-blind study to investigate the efficacy and safety of the acute use of sodium picosulphate in patients with chronic constipation. Int J Clin Pract 61 (6), 944 - 950 (2007).

P08-13256 Cullen G, O'Donoghue D. Constipation and pregnancy. Best Pract. Res. Clin. Gastroenterol. 2007; 21: 807-818.

P10-03187 Mueller-Lissner S, Kamm MA, Wald A, Hinkel U, Koehler U, Richter E, Bubeck J. Multicenter, 4-week, double-blind, randomized, placebo-controlled trial of sodium picosulfate in patients with chronic constipation. Am J Gastroenterol 105 (4), 897 - 903 (2010).

P10-11121 Roerig JL, Steffen KJ, Mitchell JE, Zunker C. Laxative abuse: epidemiology, diagnosis and management. Drugs. 2010 ;70(12):1487-503.

P11-07140 Tack J, Müller-Lisner S, Stanghellini V, Boeckxstaens G, Kamm MA, Simren M, Galmiche JP, Fried M. Diagnosis and treatment of chronic constipation – a European perspective. Neurogastroenterol Motil 2011; 23: 697-710.