Public Summary of the Risk Management Plan
Prednisolon Alternova 5 mg, 20 mg tablets
Alternova A/S
Date: 12-03-2014, version 02

VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Pradip is indicated for used for:

Non-specific anti-inflammatory and immunosuppressive therapy e.g. the following diseases:
- rheumatoid arthritis and other connective tissue diseases
- asthma
- allergic and auto-immune diseases
- some blood, kidney, liver and skin diseases, and other conditions for which systemic glucocorticoid therapy is appropriate

VI.2.2 Summary of treatment benefits

Prednisolone is a glucocorticoid used in many different states when you need to suppress an inflammatory response in the body, such as in rheumatoid arthritis (RA), inflammatory connective tissue disease (SLE), inflammation of the vessel walls, asthma, inflammation of the colon (ulcerative colitis), at certain blood diseases, severe allergic conditions and in tumor therapy.

VI.2.3 Unknowns relating to treatment benefits

Prednisolon has been used for many years and the treatment benefits are well-established in most patient-groups. However, for the following patient groups the benefits of Pradip does not outweigh the risks and the product should not be used in patients with:

- Hypersensitivity to prednisolone or any of the excipients listed in section 6.1
- Tuberculosis and other acute or chronic bacterial, fungal or viral infections unless antibiotic or chemotherapy is employed
- Acute psychosis
- Gastric and duodenal ulcer

In addition patients with the below mentioned conditions should be monitored while using Pradip:

- Osteoporosis
- Psychosis or serious mental disorders
- Diabetes mellitus
- Hypertension
- Heart failure
- Glaucoma

- Hyperthyroidism
- Recent vascular and intestinal anastomoses
- Inflammatory bowel disease and diverticulitis.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Hypersensitivity to the active substance or to any of the excipients.	Use should be contraindicated	Warnings are included in SPC and PIL. Routine Pharmacovigilance.
Pre-existing tuberculosis and other infections unless antibiotic or chemotherapy is employed.	Use should be contraindicated	Warnings are included in SPC and PIL.
Acute psychosis.	Use should be contraindicated	Routine Pharmacovigilance.
Gatric and duodenal ulcer.	Use should be contraindicated	Warnings are included in SPC and PIL.
Increase in the incidence of complications and worsening of acute and latent diseases, e.g.: • Osteoporosis • Psychosis or serious mental disorders • Diabetes mellitus • Hypertension • Heart failure • Glaucoma • Hyperthyroidism • Recent vascular and intestinal anastomoses • Inflammatory bowel disease and diverticulitis.	Patients should be monitored carefully	Warnings are included in SPC and PIL. Routine Pharmacovigilance.

Interaction with other medicinal products	Enzyme inducers increase clearance of prednisolone and reduces the half-life. The effect of anticoagulants may be decreased by prednisolone whereas concomitant use increases the risk of gastrointestinal bleeding. Caution should be exercised when anticoagulants and prednisolone are used concomitantly. The effect of antidiabetic agents may be reduced with concomitant use of prednisolone and dose adjustment may be nessassary. Concomitant use of prednisolone and NSAIDs increases the risk of gastrointestinal bleeding. Vaccines with live attenuated virus or bacteria should not be given to patients who use high-dose corticosteroid therapy due to immune deficiency caused by corticosteroid. Other vaccines may be given but the effect may be weaker due the the lack of immune response.	Warnings are included in SPC and PIL. Routine Pharmacovigilance

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

Routine pharmacovigilance activities are applied.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable

VI.2.7 Summary of changes to the risk management plan over time

Not applicable