VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Ulcerative colitis is a chronic inflammatory bowel disease and the most common type characterized by continuous mucosal inflammation that starts in the rectum and extends proximally[12, 13]. Typical presenting symptoms include bloody diarrhoea, abdominal pain, urgency, and tenesmus[12]. In patients with ulcerative colitis, the body's immune system overreacts and the body mistakes food, bacteria or other internal materials in the colon for an invading substance

Ulcerative colitis can develop at any age, but peak incidence is between the ages of 15 and 25 years, with a second, smaller peak between 55 and 65 years. Ulcerative colitis occurs in men and women at approximately equal rates[12].

VI.2.2 Summary of treatment benefits

The goals of therapy are to induce and maintain remission (the absence of symptoms) and, once that is accomplished, *maintaining* remission (prevention of flare-ups). Prednisolone decreases the risk of complications, and improves quality of life. Prednisolone Unimedic is applied topically and is used to induce remission in relapses of ulcerative colitis. Corticosteroids (prednisolone) remain first-line treatment for ulcerative colitis. Corticosteroids such as prednisolone are a more powerful type of medication used to reduce inflammation. They can be used with or instead of ASAs to treat a flare-up if ASAs alone are not effective.

VI.2.3 Unknowns relating to treatment benefits

None

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Disturbances of the endogenous cortisol balance (HPA) axis	Long-term administration of prednisolone may lead to secondary adrenocortical insufficiency. This is a condition in which a lack of adrenocorticotropic hormone (ACTH) prevents the body	A gradual reduction in dose may prevent withdrawal phenomena and allow the HPA-axis to recover.

Risk	What is known	Preventability
	from producing enough cortisol which can lead to a number of complications. The rate and duration of adrenocortical insufficiency varies among the individual patients, depending on the dose, frequency, time and duration of administration but are most frequent in the “high dose-long treatment duration patients”. Steroid "withdrawal syndrome" may be observed after abrupt discontinuation of the medicine.	
Immuno-suppression	The immunosuppressive action of prednisolone and suppression of the inflammatory response may increase susceptibility to and severity of fungal, viral and bacterial infections on the background of suppressed clinical signs and symptoms, secondary infections, activation of latent tuberculosis, as well as the disorders of the skin and subcutaneous tissue, such as impaired, delayed wound healing and skin atrophy.	Caution and specific anti-infective therapy may prevent effects of prednisolone on infections; the emergence of active tuberculosis may for example be prevented by the prophylactic use of antituberculosis therapy.
Overdose	Prednisolone is known to cause acute toxicity	Warning on overdose is included in the SmPC.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Pregnancy, lactation and fertility	It is known that the administration of corticosteroids to pregnant animals may cause abnormalities in the foetal development. There is no clinical evidence that corticosteroids may lead to increased foetal complications in humans, but their long-term or repeated administration during pregnancy may increase the risk

Risk	What is known (Including reason why it is considered a potential risk)
	of foetal development retardation. Prednisolone is excreted in small quantities to breast milk and may potentially, however not very likely, exert effects in the child. Data on the impact on fertility is lacking.

Missing information

Risk	What is known
None	Not Applicable

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 (PL). 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

Not applicable as this is the first RMP for Prednisolon Unimedic.

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

Version	Date	Safety Concerns	Comment
1	Nov 2016		Not Approved, first RMP under evaluation
1.1		Adjustment of risks to Assessors comment	