VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Vitamin B12 deficiency can have a number of possible causes. Typically it occurs in people whose digestive systems do not adequately absorb the vitamin from the foods they eat. This can be caused by: Pernicious anemia, a condition in where there is a lack of a protein called intrinsic factor. The protein, which is made in the stomach, is necessary for vitamin B12 absorption. Other causes can be gastritis, surgery in which part of the stomach and/or small intestine is removed or conditions affecting the small intestine. Vitamin B12 deficiency can also occur in pregnancy and with long-term use of acid-reducing drugs.

VI.2.2 Summary of treatment benefits

A deficiency of vitamin B_{12} (cobalamin) is manifested by fatigue, weakness, mood fluctuations, memory loss, limb weakness, difficulty walking, tingling, and paralysis. Drug treatment involves the administration of vitamin B_{12} by injection. If the deficiency of vitamin B_{12} (cobalamin) depends on the underlying disease being resolved, the vitamin supplementation continues until normal levels of vitamin B_{12} are achieved. If the deficiency state cannot be resolved (e.g. inadequate secretion of intrinsic factor, genetic abnormalities related to the site absorption, etc.) therapy should be continued for life.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Risk	**What is known**	**Preventability**
Damage to the optic nerve (atrophy)/blindness in patients with Leber´s disease (a disease that affects the optic nerve and often causes sudden vision loss in young adult carriers).	Optic nerve atrophy/blindness is a risk associated with treatment with hydroxocobalamin in patients with Leber´s disease.	The product should be used with caution.
Allergy (Hypersensitivity reactions)	Hypersensitivity may occur in patients with known hypersensitivity to hydroxycobalamin or any of the excipients	The product should not be used
Low potassium level in the blood (Hypokalemia)	Hypokalemia sometimes fatal can occur when hydroxocobalamin is used in	Serum potassium levels should be monitored in early treatment with vitamin B12

Risk	What is known	Preventability
	treatment of megalobastic anaemia.	and if necessary potassium supplements be administered..

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 Summary of Product Characteristics and the Package leaflet for Hydroxocobalamin Alternova can be found on the Danish Health and Medicines Agency after the product has been approved.

This medicine has no additional risk minimisation measures.

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.

Table 1. Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
<number>	<At time of authorisation dd/mm/yyyy>	<Identified Risks Potential Risks Missing information>	
<E.g. 7.0>	<E.g. 17/08/2012>	<E.g. Allergic conditions added as an identified risk Hypersensitivity removed as an identified risk Severe infection added as an identified risk Convulsions added as a potential risk>	<E.g. The previous term hypersensitivity was updated to allergic conditions to include angioedema and urticarial>
etc.			