VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Multiple sclerosis (MS) is a continual disease affecting the central nervous system, usually leading to early impairment in young adults. MS can occur at any age, but most people experience their first symptoms between the ages of 20 and 40 years old.

MS is relatively common in Europe, the United States, Canada, New Zealand, and parts of Australia while it is rare in Asia. The total estimated common rate of MS in Europe for the past three decades is 83 individuals per 100,000 population with higher rates in northern countries (populations farther away from the equator). MS is 2-3 times more common in women than men. Children MS is rare, accounting for about 5% of all MS cases; the average age at onset in children MS is between 12 and 14 years.
The cause (etiology) of MS is still unknown. A combination of genetic and environmental factors may be involved including higher risk with exposure to infectious agents (mainly Epstein–Barr virus) and protective effect of vitamin D.
There are several distinct subtypes of MS, including Relpasing Remitting Multiple Sclerosis (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS).
Worldwide, the most common subtype of the disease is RRMS, which affects about 85% of patients at the time of diagnosis. RRMS is characterised by unpredictable acute episodes (happens suddenly) of neurological impairment (relapses), followed by variable recovery and periods of clinical stability.

VI.2.2 Summary of treatment benefits

Overall, GA exhibited a clear beneficial effect on relapse rate, and it is based on this evidence that GA is considered effective. All studies have demonstrated that GA is well-tolerated and effective based on relevant clinical outcome measures (relapse rate), and this was confirmed by objective MRI-based outcomes.

VI.2.3 Unknowns relating to treatment benefits

In the main and supporting studies, nearly all patients were white aged between 18-65 of age. There is no evidence to suggest that results would be any different in non-white patients. From limited data available, the safety profile in paediatric patients is similar to overall population.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Immediate post injection reaction	Flushing, chest pain, shortness of breat, pounding of the heart or rapid heart rate, may occur within minutes of a GA injection. The majority of these symptoms is short-lived and resolves spontaneously.	Mechanism unknown. Treatment of such symptoms may be provided at the discretion of the treating physician.
Injection site reaction (necrosis and lipoatrophy)	In all clinical trials, injection-site reactions were seen to be the most frequent side effect and were reported by the majority of patients receiving GA.	Cases are mild, self-limiting and transient. Treatment may be provided at the discretion of the treating physician
Hypersensitivity	Severe allergic reactions have been reported rarely.	If hypersensitive reactions are severe, appropriate treatment should be instituted and GA should be discontinued.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Liver function abnormality	Abnormal liver function test was reported to be ‘common’ in clinical trials.

Important missing information

None

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

None

VI.2.6 Planned post authorisation development plan

None

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

None; this is the first RMP for GA.