WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ganciclovir 500 mg Powder for Injection [*]

Abstract

Ganciclovir 500 mg Powder for Injection, manufactured at Hainan Poly Pharm Co Ltd, No.1 Simalu, Guilinyang Economic Development Area, Lingshan, Haikou City, Hainan Province, China, was accepted for the WHO list of prequalified products on 20 December 2012 for the treatment life-threatening or sight-threatening cytomegalovirus (CMV) infections in immunocompromised individuals and for prevention of CMV disease in patients receiving immunosuppressive therapy secondary to organ transplantation.

Ganciclovir 500 mg Powder for Injection is indicated for the treatment of life-threatening or sight-threatening cytomegalovirus (CMV) retinitis in HIV-infected patients. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Ganciclovir 500 mg Powder for Injection is established and documented for the treatment of CMV infections.

The effects of intravenous ganciclovir in patients with CMV infection have been investigated in limited number of uncontrolled clinical trials. These studies have demonstrated reductions in viral load in and reduction in rates of progression in immunocompromised individuals with life- or sight-threatening CMV disease. Studies in neonates and children show that pharmacokinetics of intravenous ganciclovir is similar to that in adults. Nevertheless, the safety and effectiveness of intravenous ganciclovir in paediatric patients has not been established. Extreme caution due to long-term carcinogenicity and reproductive toxicity is warranted.

The most common adverse during treatment are haematological and include neutropenia and anaemia and. Pancytopenia, thrombocytopenia and leucopenia also occur commonly. Haematological side effects are usually reversible and may respond to treatment with colony-stimulating factors. Other very common adverse effects are dyspnoea and diarrhoea. Sepsis, cellulitis, urinary-tract infection, candidiasis, headache, fever, dermatitis, night sweats, pruritus, asthenia, gastrointestinal disturbances, dysgeusia, decreased appetite, depression, anxiety, confusion, abnormal thinking, insomnia, convulsions, dizziness, paraesthesia, myalgia, arthralgia, macular oedema, eye and ear pain, raised serum creatinine and abnormal liver function tests are commonly observed. Irritation or phlebitis may occur due to the alkality of solution.

On the basis of data submitted and public information on the use ganciclovir in CMV the team of assessors accepted Ganciclovir 500 mg Powder for Injection for the list of prequalified medicinal products.

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Ganciclovir 500 mg Powder for Injection:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	20 Dec 2012	listed				
Quality	19 Dec 2012	MR				
Bioequivalence	10 Dec 2012	MR				
Safety, Efficacy	NA	MR				
Inspection Status						
GMP(re-)inspection						
API	23 Nov 2011	MR				
FPP	16 May 2011	MR				
GCP (re-)inspection	NA	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available