WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Zincfant® 20mg

International Nonproprietary Names (INN*): zinc (as sulfate monohydrate)*

Abstract

ZinCfant® 20mg, manufactured at Laboratoires Pharmaceutiques Rodael, Bierne, France, was accepted for the WHO list of prequalified medicinal products for the treatment of Diarrhoea on 04 December 2012.

ZinCfant® 20mg contains zinc, an essential trace element.
ZinCfant® dispersible tablets are a rapidly dispersible tablet formulation of zinc sulfate monohydrate equivalent to 20 mg of elemental zinc. ZinCfant tablets are indicated for the treatment of acute and persistent diarrhoea in children and infants less than 5 years of age.

Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

Efficacy and safety of zinc in the management of diarrhoea in children have been shown in a number of clinical studies, leading the WHO and UNICEF to issue a joint statement recommending the use of zinc in the clinical management of acute diarrhoea.

The most frequent adverse events are vomiting and regurgitation. Also, abdominal pain and dyspepsia have been reported.

On the basis of data submitted and public information on the use of zinc in diarrhoea, the team of assessors advised that ZinCfant® 20mg is of acceptable quality, efficacy and safety to allow inclusion of the product in the list of prequalified medicinal products.

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* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for ZinCfant® 20mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	04 Dec 2012	listed				
Dossier Evaluation (Quality assurance)						
Quality	26 Nov 2012	MR				
Bioequivalence	NA	NA				
Safety, Efficacy	25 Sept 2012	MR				
Inspection Status						
GMP(re-)inspection						
API	NA	MR				
FPP	07 Oct 2010	MR				
GCP (re-)inspection	NA	NA				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available