WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Zinc (as sulfate) Dispersible Tablets 20 mg*

Abstract

Zinc (as sulfate) Dispersible Tablets 20 mg manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh,, India, was included in the WHO list of prequalified products for the treatment of diarrhoea on 7 December 2016.

Zinc (as sulfate) Dispersible Tablets 20 mg contains zinc, an essential trace element. The rapidly dispersible tablet formulation contains zinc sulfate monohydrate equivalent to 20 mg of elemental zinc. Zinc (as sulfate) Dispersible Tablets 20 mg is indicated for the treatment of acute and persistent diarrhoea in children and infants aged less than 5 years.

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 Zinc (as sulfate) Dispersible Tablets 20 mg is of acceptable quality, efficacy and safety to allow its inclusion of the product in the list of prequalified medicinal products

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

Summary of Prequalification Status for Zinc (as sulfate) Dispersible Tablets 20 mg:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	**07 Dec 2016**	**listed**				
Dossier Evaluation (Quality assurance)						
Quality	**02 Dec 2016**	**MR**				
Bioequivalence	**05 Aug 2015**	**MR**				
Safety, Efficacy	**NA**	**NA**				
Inspection Status						
GMP (re-)inspection						
API	**18 July 2016**	**MR**				
FPP	**17 July 2014**	**MR**				
GCP/GLP (re)inspection	**NA**	**NA**				

MR: meets requirements

NA: not applicable, not available