WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

VERMOX CHEWABLE[1] 500 mg chewable tablets

Mebendazole

Abstract

Vermox Chewable, manufactured at Lusomedicamenta Sociedade Técnica Farmacêutica S.A.; Barcarena, Portugal was included in the WHO list of prequalified medicinal products for large scale preventive chemotherapy interventions for the control of soil-transmitted helminth infections on 5 April 2019.

Vermox Chewable is indicated for indicated for the mass treatment of subjects one year of age and older with gastrointestinal infections caused by *Ascaris lumbricoides* (roundworm), *Trichuris trichiura* (whipworm), *Necator americanus* and *Ancylostoma duodenale* (hookworms).
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 Vermox Chewable is mebendazole.

Adverse events observed during treatment with mebendazole were anorexia, abdominal pain, diarrhoea, flatulence, nausea, vomiting and rash.

The efficacy and safety profile of mebendazole is well established based on extensive clinical experience in preventive chemotherapy of soil-transmitted helminth infections.

On the basis of data submitted and public information on the use of mebendazole in soil-transmitted helminth infections, the team of assessors advised that Vermox Chewable 500mg chewable tablets is of acceptable quality, efficacy and safety to allow its inclusion in the list of prequalified medicinal products.

[1] 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 VERMOX CHEWABLE:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	05 April 2019	listed
Quality	27 March 2019	MR
Bioequivalence	22 March 2019	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection*		
API	NA	NA
FPP	NA	NA
GCP/GLP (re-)inspection*	NA	NA

MR::meets requirements
NA: not applicable, not available
* Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority showed acceptable outcome.