WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Diethylcarbamazine Citrate Tablets 100 mg USP*

International Nonproprietary Name (INN): *Diethylcarbamazine citrate*

Abstract

Diethylcarbamazine Citrate Tablets 100 mg USP, manufactured at Eisai Pharmatechnology and Manufacturing Pvt. Limited, Andhra Pradesh, India, were accepted for the WHO list of prequalified medicinal products for the large scale preventative chemotherapy interventions for the control of lymphatic filariasis on 20 August 2013.

Diethylcarbamazine Citrate Tablets 100 mg USP contain diethylcarbamazine citrate, a synthetic piperazine derivative with an antihelmintic action. It has the potential to interrupt the parasitic life cycle by destruction of microfilariae which are essential for host to vector transmission of the parasite. There is evidence to suggest that diethylcarbamazine is also macrofilaricidal.

Studies of mass drug administration (MDA) in adults and in children over 2 years of age have shown that diethylcarbamazine citrate in combination with albendazole reduced microfilaraemia in endemic populations, when administered as a single-dose, once-yearly treatment.

Efficacy and safety of diethylcarbamazine citrate in combination with albendazole in MDA programmes have been shown in a number of clinical studies in different geographical regions, leading to the inclusion of this regimen in the recommendations of the WHO Global Programme to Eliminate Lymphatic Filariasis.

For safety reasons diethylcarbamazine citrate must only be used in areas where where onchocerciasis is not co-endemic.

In the absence of circulating microfilaraemia, the administration of diethylcarbamazine citrate, when given at the recommended dosage, may cause nausea, vomiting, abdominal pain, diarrhoea, loss of appetite, muscle pain, dizziness, drowsiness, fatigue and headache.

In patients with circulating microfilaraemia adverse reactions may be more common and severe, particularly in patients with a high parasite burden. These are considered allergic reactions due to antigen-antibody reaction caused by dead microfilariae or adult filarial worms. The intensity and the severity of adverse reactions are usually associated with the level of microfilariaemia in the blood prior to treatment.

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

On the basis of data submitted and public information on the use of diethylcarbamazine citrate as intervention for the control of lymphatic filariasis, the team of assessors advised that Diethylcarbamazine Citrate Tablets 100 mg USP are 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 the local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for Diethylcarbamazine Citrate Tablets 100 mg USP:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	20 Aug 2013	listed				
Dossier Evaluation (Quality assurance)						
Quality	04 Aug 2013	MR				
Bioequivalence	02 July 2013	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	NA	MR				
FPP	24 Jan 2013	MR				
GCP (re-)inspection	NA	MR				
Batch Analysis	NA	NA				

MR: meets requirements
NA: not applicable, not available