WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Dexametasona Kern Pharma 4 mg/ml solución inyectable [1]

International Nonproprietary Name (INN):
Dexamethasone phosphate 4mg/ml Solution for Injection

Abstract

Dexametasona Kern Pharma 4 mg/ml solución inyectable manufactured at Kern Pharma, S.L. was submitted to be considered for prequalification in 2014 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 13 Aug 2014.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the Spanish Authority "AEMPS" (http://www.aemps.gob.es/), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities".[3]

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

Based on the above, this WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification. Detailed information on the SRA-approved use of this product is described in the Summary of Product Characteristics (SmPC), which is a company authorized English translation of the Spanish SmPC "and can be found in this WHOPAR. The most recent authorized Spanish product information can be requested from the Spanish Medicines Regulatory Agency (http://www.aemps.gob.es/ http://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=buscar last accessed Nov 2015).

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Dexametasona Kern Pharma 4 mg/ml solución inyectable are included here.

Dexametasona Kern Pharma 4 mg/ml solución inyectable contains dexamethasone. Its WHO recommended use is for the treatment of steroid- responsive conditions in HIV/AIDS patients.

The most frequent adverse events observed during treatment with dexamethasone were increased susceptibility to infections, hyperglycaemia, adrenocortical insufficiency, polyphagia, cataracts, delayed wound healing, local allergic reaction, osteoporosis and bone fragility.

[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
[2] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf

At high doses: Cushing's syndrome, hot flashes, gastric ulcer, hirsutism, cutaneous, hyperpigmentation and scleroderma.

The most serious adverse effects of dexamethasone are intracranial hypertension, neuropsychiatric disorders, heart failure and thromboembolism.
With long-term administration: avascular necrosis, steroidal myopathy, striae, tendon rupture, osteoporosis, pancreatitis and intestinal perforation.

The efficacy and safety profile of dexamethasone is well established based on the extensive clinical experience in the treatment of steroid- responsive conditions.

Summary of Prequalification Status for
Dexametasona Kern Pharma 4 mg/ml solución inyectable

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	13 Aug 2014	listed		
Dossier Evaluation	07 July 2014	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.