WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Bactrim 400 mg/80 mg tablets[1]

Sulfamethoxazole/Trimethoprim 400mg/80mg tablets

Bactrim 400 mg/80 mg tablets was submitted in 2019 by. Roche AB, Sweden to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 17 December 2019.
Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information (https://extranet.who.int/prequal/medicines/ha747).

The applicant transferred to Eumedica Pharmaceuticals AG in March 2021.

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 Team: Medicines (PQTm), is based on the approval by the Swedish Medical Products Agency "lakemedelsverket" (https://www.lakemedelsverket.se/en), 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.
However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Do not store above 30°C. Store in the original package.
- The shelf-life at this storage condition is 60 months.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility Throughout this WHOPAR the proprietary name is given as an example only.
*Formerly Roche AB

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.
(https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel?id=19721020000044
MT-nummer 8675)

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet.
The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "Läkemedelsverket" approved texts, are included in this WHOPAR.
This WHOPAR for Bactrim 400 mg/80 mg tablets comprises the parts 2, 3. 4. 5 and 7.

Bactrim 400 mg/80 mg tablets contain sulfamethoxazole and trimethoprim.
Its WHO recommended use is for the treatment and prophylaxis of opportunistic infections in HIV infected patients.

The efficacy and safety profile of sulfamethoxazole and trimethoprim is well established based on the extensive clinical experience in the treatment and prevention of infections in HIV/AIDS patients.

Summary of Prequalification Status for Bactrim 400 mg/80 mg tablets

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 December 2019	listed
Quality	November 2019	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.