WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Darunavir (as ethanolate) 800 mg Tablets

International Nonproprietary Name (INN):
Darunavir ethanolate

Abstract

Darunavir (as ethanolate) 800mg Tablets, manufactured at Cipla Limited, Unit –II, A-42, MIDC, Patalganga 410220, District-Raigad, Maharashtra, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 31 October 2018.

Darunavir (as ethanolate) 800mg Tablets co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescent patients weighing at least 40 kg. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

Darunavir (as ethanolate) 800 mg Tablets should be prescribed and administered in accordance with countries’ national laws and regulations.

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The most frequent adverse events observed during treatment are diarrhoea, headache, nausea, rash, abdominal pain and vomiting.

The most serious adverse events reported are diabetes mellitus, peripheral neuropathy, allergic dermatitis, myalgia, and drug hypersensitivity.

The efficacy and safety profile of Darunavir (as ethanolate) 800 mg Tablets is well-established, based on extensive clinical experience in the treatment of HIV infection.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors advised that Darunavir (as ethanolate) 800 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Darunavir (as ethanolate) 800mg Tablets 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 Darunavir (as ethanolate) 800 mg Tablets:

<table>
<thead>
<tr>
<th>Initial acceptance</th>
<th>Date</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>Status on PQ list</td>
<td>31 October 2018</td>
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<tr>
<td>Quality</td>
<td>25 April 2017</td>
<td>MR</td>
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<td>Bioequivalence</td>
<td>04 October 2018</td>
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<td>Safety, Efficacy</td>
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<td>NA</td>
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<td>GCP/GLP (re-)inspection</td>
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MR: meets requirements  
MR*: desk review (based on recent inspection reports)  
NA: not applicable, not available