COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Darunavir Vivanta 400 mg, 600 mg and 800 mg film-coated tablets

(darunavir)

NL/H/4522/001-003/DC

Date: 15 January 2020

This module reflects the scientific discussion for the non-approval of Darunavir Vivanta 400 mg, 600 mg and 800 mg film-coated tablets. The procedure was finalised at 3 October 2019.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Darunavir Vivanta 400 mg, 600 mg and 800 mg film-coated tablets, from Vivanta Generics s.r.o.

The indications applied for concerns:
Darunavir Vivanta 600 mg tablets may be used to provide suitable dose regimens:

- For the treatment of HIV-1 infection in antiretroviral treatment (ART)-experienced adult patients, including those that has been highly pre-treated.
- For the treatment of HIV-1 infection in paediatric patients from the age of 3 years and at least 15 kg body weight.

In deciding to initiate treatment with these strengths co-administered with low dose ritonavir, careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of these products.

Darunvar Vivanta 400 and 800 mg tablets may be used to provide suitable dose regimens for the treatment of HIV-1 infection in adult and paediatric patients from the age of 3 years and at least 40 kg body weight who are:

- Antiretroviral therapy (ART)-naïve.
- ART-experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA <100,000 copies/ml and CD4+ cell count ≥ 100 cells x 106/l. In deciding to initiate treatment with Darunavir in such ART-experienced patients, genotypic testing should guide the use of Darunavir.

The marketing authorisation was applied pursuant to Article 10(1) of Directive 2001/83/EC.

The concerned member states (CMS) involved in this procedure were Germany, Spain, France and Italy.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to a potential serious risk to public health as defined in the Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC — March 2006 (2006/C 133/05).

Quality

The chemical-pharmaceutical documentation in relation to Darunavir Vivanta is not of sufficient quality in view of the present European regulatory requirements. This was concluded as it was not possible to grant a shelf life to the product, because a specific dissolution requirement was not met. This conclusion has been based on the available dissolution test results in stability samples.

Therefore, the Board concluded that the marketing authorisation for Darunavir Vivanta 400 mg, 600 mg and 800 mg film-coated tablets cannot be granted. Agreement on this conclusion was reached with the concerned member states. The decentralised procedure was finalised with a negative outcome on 3 October 2019.