فرع شركة جونسون أند جونسون ميدل إيست

Direct Healthcare Professional Communication

29-August-2018

Increased risk of treatment failure and an increased risk of mother to child transmission of HIV infection due to low exposure values of darunavir and cobicistat during the second and third trimesters of pregnancy.

Dear Healthcare Professional,

Janssen, Pharmaceutical company of Johnson & Johnson, in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Summary

- **Therapy with darunavir/cobicistat should not be initiated during pregnancy.**
- **Women who become pregnant during therapy with darunavir/cobicistat should be switched to an alternative regimen: darunavir/ritonavir may be considered as an alternative.**
- **This is because pharmacokinetic data showed low exposure values of darunavir and cobicistat during the second and third trimesters of pregnancy.**
- **Low darunavir exposure may be associated with an increased risk of treatment failure and an increased risk of mother to child transmission of HIV infection.**

Background

The pharmacokinetic data from the Phase 3b study TMC114HIV3015 in 6 pregnant women demonstrated that the mean exposure (AUC) of darunavir boosted with cobicistat was 56% and 50% lower during the 2nd and 3rd trimesters of pregnancy, respectively, compared with 6 to 12 weeks postpartum. Mean darunavir C_{min} concentrations were around 90% lower during the 2nd and 3rd trimesters of pregnancy as compared to postpartum. Exposure of cobicistat was 63% and 49% lower during the 2nd and 3rd trimesters of pregnancy, respectively, as compared to postpartum.

Low darunavir exposure may be associated with an increased risk of treatment failure and an increased risk of HIV-1 transmission to the child. Therefore, therapy with darunavir/cobicistat should not be initiated during pregnancy and women who become pregnant during therapy with darunavir/cobicistat should be switched to an alternative regimen.

Based upon this information, the product information for PREZISTA has been updated.

The information in this letter has been approved by Saudi Food & Drug Authority (SFDA).

Johnson & Johnson Middle East FZ Branch
C.R. No. 1010609567 - C.C. No. 415004
Mawheba Building, 3rd Floor, Al-Olaya Road, Al Wrood District
P.O.Box: 55031 Riyadh: 11533 Kingdom of Saudi Arabia
Tel : +966 11 419 7966 , Fax: +966 11 215 3190

فرع شركة جونسون أند جونسون ميدل إيست
رقم السجل التجاري: ١٠١٠٦٠٩٥٦٧ - رقم المضوية: ٤١٥٠٠٤
مركز موهبة - الطابق الثالث - شارع العليا - حي الورود
الرياض المملكة العربية السعودية ص. ب ٥٥٠٣١ الرياض ١١٥٣٣
هاتف: +٩٦٦ ١١ ٤١٩٧٩٦٦ ، فاكس: +٩٦٦ ١١ ٢١٥٣١٩٠

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Contact information

Healthcare professionals are encouraged to report adverse events in patients taking PREZISTA in accordance with the national spontaneous reporting system.

SFDA (National Pharmacovigilance and Drug Safety Department)
Email to: npc.drug@sfda.gov.sa
Telephone: 8002490000
Fax: +966-11-2057662
Online: http://ade.sfda.gov.sa

If you have further questions or require additional information, please contact our Local Safety Department at:
Email: GCC-PV2@its.jnj.com
Fax: +966-11-2153190

Yours faithfuliy,

3. Sep. 2018

Hesham Atef
Medical Affairs Director-GCC