

27 May 2010

Ref: P20/5/10

Direct Healthcare Professional Communication on the need for close monitoring of International Normalised Ratio (INR) with Warfarin Teva Tablets if this preparation replaces or is replaced by another warfarin product

Dear Healthcare Professional,

Teva, in agreement with the IMB, wishes to remind healthcare professionals of the importance of close monitoring of the International Normalised Ratio (INR) in all patients when switching between brands of warfarin tablets.

Warfarin Teva was launched in Ireland in December 2008 and close monitoring of the INR is essential to ensure its safe and appropriate use, in accordance with the Summary of Product Characteristics (SmPC) recommendations, detailed below.

Since launch of this product, there have been rare reports of adverse reactions documenting clinically significant variations in INR levels, in the absence of dose changes associated with treatment switches. Close monitoring of the INR is recommended particularly in the period immediately after the warfarin brand change. This advice is consistent with the SmPC which is attached to this communication (and may also be accessed online at www.imb.ie):

- If Teva Warfarin replaces or is replaced by another warfarin product, INR should be monitored closely in the period immediately following the change. Patients should be told what to do if bleeding occurs.
- When commencing therapy with Warfarin, INR values should be obtained daily or on alternate days during the early stages. When the dose has been established and the patient has stable INR values, the INR can be monitored at longer but regular intervals, as appropriate. Patients should be instructed on measures to minimise risk of bleeding and to report immediately to physicians signs and symptoms of bleeding.
- The most frequently reported adverse effect of all oral anticoagulants is haemorrhage. Risk factors for bleeding include high intensity of anticoagulation, age ≥ 65 , history of gastrointestinal bleeding, impaired hepatic function, vitamin K deficiency and other hypermetabolic states, uncontrolled hypertension, cerebrovascular disease, serious heart disease, malignancy, renal insufficiency, concomitant drugs (see sections 4.4, 4.5 and 4.8 of the SmPC).
- Checking the INR and reducing or omitting doses depending on INR level is essential following consultation with anticoagulation services if necessary. If

the INR is found to be above the desired therapeutic range, the dose of warfarin should be reduced or stopped. INR should be checked within 2-3 days to ensure that it is decreasing. Any concomitant anti-platelet drugs should be used with caution due to an increased risk of bleeding.

Teva have made available Patient Switch Cards (to be completed by pharmacists for patients to take to their INR clinic) to ensure that patients who are switched to Warfarin Teva are monitored appropriately. A sample of the Patient Switch Card is enclosed, and additional copies are available on request from Teva Pharmaceuticals Ireland (Freephone 1800 201 700).

Reporting recommendations


Healthcare professionals should report any suspected adverse reactions associated with use of Warfarin Teva tablets, including any drift from the desired therapeutic INR range in the absence of a dosage change to the distributor of the product, Teva Pharmaceuticals Ireland, through the contact details listed below. Adverse reactions may also be reported to the Irish Medicines Board using the spontaneous reporting system or online at www.imb.ie.

Contact Details

Pharmacovigilance Unit
Teva Pharmaceuticals Ireland
IDA Industrial Park
Waterford

Telephone: + 353 (0) 51 331 331 (ext. 2180 / 2182)
Fax: + 353 (0) 51 359 805
Mob: + 353 (0) 87 677 3650
Email: safety.ireland@teva.ie

If you should require any further information in relation to this communication, please contact our Medical Information Unit (Telephone: +44 (0)207 540 7117, Email: medinfo@tevauk.com).


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