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Press Office

Press release

European Medicines Agency agrees to precautionary recall of Advagraf 0.5 mg capsule batches

Defect unlikely to have caused safety issues

The European Medicines Agency has agreed to the immediate recall of some batches of 0.5 mg prolonged-release hard capsules of Advagraf (tacrolimus) from pharmacies and wholesalers across the European Union (EU). This follows detection of more active substance than expected being released from the capsules.

The available information does not suggest that the defect is linked to clinical adverse events. However, the recall is being conducted as a precautionary measure because the defect could have led to slightly higher levels of tacrolimus in the blood of patients taking the affected capsules.

Doctors are advised to consider the potential impact on blood tacrolimus levels when monitoring patients who may have taken capsules from the defective batches, especially those taking maintenance therapy with a daily dose of 0.5 mg. Raised blood levels of the medicine may also have occurred in patients also taking medicines that slow down the breakdown of tacrolimus in the body, such as the antifungal medicine fluconazole or protease inhibitors for HIV infection including ritonavir.

The defect was detected during routine testing by the marketing-authorisation holder, Astellas. The company found that during the first 1.5 hours of dissolution testing, an average of 70% of the tacrolimus in the capsules was released. This was above the permitted range of 48% to 68%.

The recall is not expected to affect the overall supply of Advagraf. It only affects batches derived from one parent batch of Advagraf 0.5 mg prolonged-release hard capsules. Astellas has informed the Agency that replacement batches are available.

Advagraf is used to prevent organ rejection in adults who have had a kidney or liver transplant or to treat organ rejection when other medicines have not worked.

According to the information provided to the Agency, the affected batches were distributed to a number of countries across the EU. Romania and the United Kingdom are estimated to have the most stock of affected capsules remaining.

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The Agency's Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Working Party (PhVWP) have agreed to the texts of letters to pharmacists and prescribers explaining the recall. Astellas will be sending these letters within the next few days.

Patients who have any concerns should speak to their doctor or pharmacist.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The batches being recalled are 0M3006A, 0M3006F, 0M4006K, 0M3006P, 0M4006N, 0M4006E, 0M4006C, 0M6006T, 0M4006L, 0M4006B, 0M4006R and 0M3006M.
3. All other opinions and documents adopted by the CHMP at its October 2011 plenary meeting will be published on Friday, 21 October 2011 at 12.00 noon UK time on a dedicated web page.
4. More information on Advagraf is available on the Agency's website.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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