EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2017
EMA/CHMP/661981/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tacforius

tacrolimus

On 12 October 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tacforius, intended for prophylaxis and treatment of transplant rejection. The applicant for this medicinal product is Teva B.V.

Tacforius will be available as prolonged-release capsules (0.5 mg, 1 mg, 3 mg and 5 mg). The active substance of Tacforius is tacrolimus, a macrolide immunosuppressant medicinal product (ATC code: L04AD02) that inhibits the activation of the serine-threonine phosphatase, calcineurin, in T lymphocytes. This suppresses T lymphocyte activation and the subsequent generation of cytotoxic lymphocytes, thereby down regulating processes leading to acute graft rejection. T-helper cell-dependent B cell proliferation is also affected.

Tacforius is a generic of Advagraf, which has been authorised in the EU since 25 April 2007. Studies have demonstrated the satisfactory quality of Tacforius, and its bioequivalence to the reference product Advagraf. A question and answer document on generic medicines can be found here.

The full indication is: "Prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients".

Tacforius therapy requires careful monitoring by adequately qualified and equipped personnel. The medicinal product should only be prescribed, and changes in immunosuppressive therapy initiated, by physicians experienced in immunosuppressive therapy and the management of transplant patients.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact