

18-March-2025

European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands.

Subject: Withdrawal of Sirolimus TriviumVet 0.4 mg, 1.2 mg, and 2.4 mg tablets for cats: Indicated for reduction of left ventricular hypertrophy in cats with subclinical HCM (V0006230).

Dear Sirs,

I would like to inform you that, at this point in time, Triviumvet DAC (TriviumVet) has taken the decision to withdraw the application for Marketing Authorisation of Sirolimus TriviumVet, sirolimus 0.4 mg, 1.2 mg, and 2.4 mg tablets for cats, which was intended to be used for the reduction of left ventricular hypertrophy in cats with subclinical HCM.

The withdrawal is based on the reason that the CVMP considers that the data provided does not allow the committee to conclude on a positive benefit risk balance.

We reserve the right to make further submissions at a future date in this or other therapeutic indications(s)/target species if applicable.

I agree for this letter to be published on the EMA website.

