



20.02.2019

Information regarding Everolimus Stada 2,5 mg, 5 mg und 10 mg tablets

Following the grant of the marketing authorization, STADA Nordics ApS is launching Everolimus Stada in Denmark.

The patent protection (SPC No. CA 2004 00020 based on EP 0 663 916 B1 to Novartis) for the substance Everolimus expired on 18.01.2019.

Novartis still owns the patent EP 3 143 995 B1, which covers the use of the substance Everolimus in the treatment of a solid tumor of lung other than lymphatic cancer. The Danish part of EP 3 143 995 B1 will expire on 18.02.2022.

Furthermore, EP 2 269 604 B1 to Novartis covers the use of the substance Everolimus in the treatment of solid tumors other than lymphatic cancer, wherein the solid tumor is a kidney tumor. The Danish part of EP 2 269 604 B1 will expire on 18.02.2022.

The use of Everolimus Stada:

The purpose of this letter is to notify you, that Everolimus Stada is not indicated for the treatment of patients with neuroendocrine tumors of gastrointestinal or lung origin and also not for the treatment of patients with renal cell carcinoma. Everolimus Stada should not be prescribed nor dispensed for these indications as long as the Danish parts of the above mentioned patents are in force. Therefore, STADA Nordics ApS has not included these indications neither in its Summary of Product Characteristics nor in its Patient Information Leaflet.

Notwithstanding the aforementioned, STADA Nordics ApS may decide to include said indications, if it comes to the conclusion, in the future, that these rights are null or non-infringed.

Please be so kind to ensure that the content of this letter is communicated to the respective doctors of the Oncology Service, as well as to the Pharmacy Service, so that they will refrain from prescribing or dispensing Everolimus Stada for the treatment of patients with neuroendocrine tumors of gastrointestinal or lung origin, as well as for the treatment of patients with renal cell carcinoma.

Yours sincerely,

A handwritten signature in blue ink, appearing to be "Henriette Kalmeyer", written over a light blue horizontal line.

Questions

For questions in relation to STADA Nordics ApS, please contact:
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