

4/9/19

Information regarding Dasatinib Stada 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg tablets

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

The active ingredient Dasatinib per se is patent-free.

Bristol Myers Squibb Holdings Ireland owns the patent EP 1 610 780 B1, which covers the use of the substance Dasatinib in the treatment of cancer, i.a. of chronic myelogenous leukemia (CML). The Danish part of EP 1 610 780 B1 will expire on 23.03.2024.

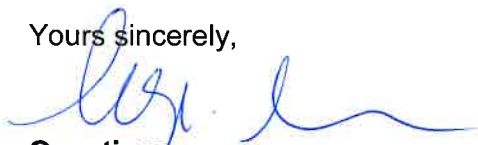
The use of Dasatinib Stada:

The purpose of this letter is to notify you, that Dasatinib Stada is not indicated for the treatment of patients with CML. Dasatinib Stada should not be prescribed nor dispensed for these indications as long as the Danish part of the above mentioned patent is in force. Therefore, STADA Nordics ApS has not included this indication neither in its Summary of Product Characteristics nor in its Patient Information Leaflet.

Notwithstanding the aforementioned, STADA Nordics ApS may decide to include said indication, if it comes to the conclusion, in the future, that EP 1 610 780 B1 is 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 Dasatinib Stada for the treatment of patients with CML.

Yours sincerely,



Questions

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

Jette Qvade S eberg

js@stada.dk