Pfizer Laboratories (Pty) Ltd
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IMPORTANT MEDICINE SAFETY INFORMATION

02 September 2019

Dear Healthcare Professional,

Notification of important new information regarding treatment of patients with antiphospholipid syndrome (APS) with Eliquis: Increased risk of thrombo-embolic events

Pfizer Laboratories (Pty) Ltd, in agreement with South African Health Products Regulatory Authority (SAHPRA), would like to inform you of the following changes to the Professional Information of Eliquis (apixaban).
As contraindication: Patients with anti-phospholipid syndrome (APS) with persistent positivity for all three anti-phospholipid antibodies (patients with triple positive APS).
In the Warnings and Special Precautions section: Treatment of patients with established APS is not recommended as evidence regarding safety and efficacy, including the benefit/harm balance of apixaban in patients with APS, is inconclusive/incomplete. There is some evidence that treatment with apixaban may be associated with an increased risk of recurrent arterial thrombotic events in patients with APS compared to treatment of these patients with Warfarin, a vitamin K antagonist.

Background on the safety concern
There is limited data available for apixaban as there are no completed clinical trials of this product in patients with a clinical diagnosis of APS.

The protocol of the "Apixaban for the Secondary Prevention of Thrombosis among Patients with Antiphospholipid Syndrome (ASTRO-APS) study" - where patients received therapeutic anticoagulation to either dose-adjusted warfarin or apixaban 2.5 mg twice a day, had to be amended twice as a result of an increased incidence of arterial thrombotic events in the apixaban arm compared to the Warfarin arm of the study. This study is still ongoing, and no further analysis of results is available.

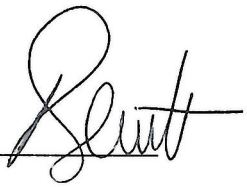
Call for reporting

For further information, please contact the individual noted below:

Company	Product name	Active Ingredient(s)	Registration Number	Contact Details
Pfizer Laboratories (Pty) Ltd	Eliquis® 2,5 mg Eliquis® 5 mg	Apixaban Apixaban	47/8.2/0463 47/8.2/0464	Puvinesvarie Naidoo Pfizer Laboratories (Pty) Ltd Responsible Pharmacist (011) 320 6000

Healthcare Professionals should report all suspected adverse events associated with apixaban to the contact indicated above, or to the SAHPRA Pretoria Office at Tel: 012 842 7609/10, Email: adr@sahpra.org.za or the National Adverse Drug Event Monitoring Centre at Tel: 021 447 1618 or Fax 021 448 6181.

Yours faithfully,



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