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AstraZeneca receives CDSCO approval to market Andexanet Alfa in India for critical bleeding conditions

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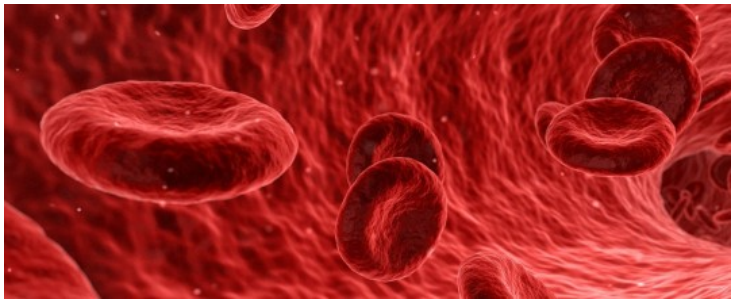
Making medicine available for patients on FXa inhibitors who have life-threatening or uncontrolled bleeding



AstraZeneca Pharma India has received approval from Central Drugs Standard Control Organisation (CDSCO) in India for the import and marketing of Andexanet Alfa. This ground-breaking treatment addresses life-threatening or refractory bleeding associated with the use of Factor Xa (FXa) inhibitors.

FXa inhibitors are increasingly employed for preventing and treating thrombotic events, such as deep vein thrombosis and pulmonary embolism, as well as in patients at high risk of stroke due to atrial fibrillation. While these medications effectively prevent unwanted clot formation, they also elevate the risk of major bleeding, which can be life-threatening.

The rise in the use of FXa inhibitors highlights the necessity for a specific reversal agent to mitigate the morbidity and mortality associated with major bleeding. Andexanet Alfa has demonstrated both efficacy and safety in clinical trials involving healthy subjects and patients with major life-threatening bleeding.

Dr Anil Kukreja, Vice-President, Medical Affairs and Regulatory, AstraZeneca India, said, “Major bleeding occurs in approximately 4-6% of patients treated with oral FXa inhibitors, and Andexanet Alfa stands as the sole reversal agent authorized for individuals undergoing treatment with apixaban or rivaroxaban facing life-threatening or refractory bleeding.”

Andexanet Alfa is a novel and life-saving antidote designed to reverse the effects of anticoagulant medications in emergency situations. It is well-tolerated and facilitates the early restart of anticoagulation following a bleeding event. The therapy is administered through an intravenous (IV) bolus over a duration of 15–30 minutes, followed by a 2-hour infusion.