Boehringer Ingelheim

10 August 2018

Actilyse (Alteplase) in Acute Ischaemic Stroke: Important information on extension to use in adolescents (≥16 years) and request for data collection

Dear Healthcare Professional,

Boehringer Ingelheim and the Medicines and Healthcare products Regulatory Agency would like to inform you of the following important information regarding the recent extension of the licence to include use of Actilyse® (alteplase) in adolescents ≥16 years in the acute ischaemic stroke indication:

Summary

- **The licence extension is based on observational, non-randomised and non-comparative data in stroke patients of 16 -17 years of age with confirmed alteplase treatment (data source SITS-ISTR; Safe Implementation of Treatments in Stroke - International Stroke Thrombolysis Register).**
- **Since the frequency of stroke in adolescents ≥16 years of age is low, collection of further data on safety and efficacy in this population is very important. Therefore, it is highly recommended to register and submit data to the independent SITS environment under http://www.sitsinternational.org/.**
- **Actilyse® is contraindicated for the treatment of acute ischaemic stroke in children and adolescents under 16 years of age.**

Further information

- The SITS registry is an independent international medical-scientific stroke network/platform which collects outcome data from patients with an acute ischemic stroke who were treated with Actilyse®. This independent registry is open to all interested centres/hospitals which wish to participate after online registration.
- Prior to Actilyse® treatment in an adolescent patient ≥16 years, stroke mimics should be ruled out and the thromboembolic ischaemic lesion should be confirmed by appropriate neuroimaging techniques.
- For information on the data supporting the licence extension to include adolescents ≥16 years of age, refer to section 5.1 of the current Summary of Product Characteristics (SmPC).

SITS registry and the call for data collection on paediatric patients

Boehringer Ingelheim and the Medicines and Healthcare products Regulatory Agency consider that further structured data collection is desirable to further evaluate the effects of alteplase in adolescents ≥16 years. The SITS is an initiative by an independent international medical-scientific stroke network to assure excellence in acute treatment and secondary prevention of stroke, as well as to facilitate clinical trials.
The SITS registry is active in over 80 countries on five continents, which makes SITS a world-leading stroke network.
SITS Registry is a free of charge service and available to any hospital or clinic that admits and treats TIA and stroke patients. This is regardless of the number of patients admitted, patient capacity or if a stroke unit currently exists. Anyone who applies to the Registry for a new centre has to be an authorized physician in charge of the stroke unit and/or care of their clinic. This person should be appointed by the Medical head of the department and will represent the hospital/clinic in connection with SITS. All research staff at an approved centre can also join SITS.
If you or your institution use or plan to use Actilyse® in adolescent patients ≥16 years of age for the treatment of an acute ischemic stroke please visit the SITS homepage http://www.sitsinternational.org/ and follow either the "join SITS" link in the upper right corner or log in and submit your data to the database. If you are new to the SITS registry, instructions on the homepage will guide you through the registration process and will support you in the approval process and in data entry.

Summary of Product Characteristics (SmPC) for Actilyse® with information on adolescents can be accessed via the eMC website.

Call for reporting

Healthcare professionals should report any adverse events suspected to be associated with the use of Actilyse® via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone) or by email to PV_local_uk_ireland@boehringer-ingelheim.com.

Company contact point

For further medical information on Actilyse®, please contact Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS, United Kingdom;
Tel: +44 (0) 1344 742579; E-mail: medinfo.bra@boehringer-ingelheim.com.

Yours faithfully,

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