1st August 2020

Dear Healthcare Professional,

RE: FIRAZYR® (icatibant acetate) AUST R 160313 to be withdrawn from the Pharmaceutical Benefits Scheme (PBS) and commercial supply in Australia discontinued

This letter is to inform you that, from 1st October 2020, the FIRAZYR brand of icatibant acetate will no longer be listed on the Pharmaceutical Benefits Scheme (PBS) and will no longer be commercially supplied in Australia.

Australian patients will still be able to access icatibant acetate on the PBS. A generic form of icatibant acetate will be listed on the PBS from 1st October 2020. Takeda Australia has been assured by the Department of Health that sufficient supplies of generic icatibant acetate will be available to meet the existing demand from 1st October 2020. We encourage all prescribers to contact their patients to discuss this upcoming change in brand availability.

For patients who are treated with FIRAZYR on a compassionate basis, Takeda will proactively contact the relevant prescribers to discuss plans for post 1st October 2020.

For additional information, please contact Takeda Medical Information via phone on 1800 012 612 or email: medinfoAPAC@takeda.com. Adverse events related to FIRAZYR (icatibant acetate) treatment should be reported by healthcare professionals to the Takeda Australia Pharmacovigilance department on 1800 012 612 or by email to drugsafety@shire.com. Alternatively, this information can be reported to the TGA.

Yours sincerely,

Brad Edwards

General Manager

Takeda Pharmaceuticals Australia Pty Ltd, Sydney, NSW 2000.
Tel: 1800 012 612. Email: medinfoAPAC@takeda.com ABN 71 095 610 870.

Date of Preparation July 2020. C-APROM/AU//1260

Please review Approved Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd https://www.takeda.com/en-au/what-we-do/our-products/

PBS Information: Authority required. Refer to PBS schedule for full authority requirement information

Minimum Product Information FIRAZYR® (icatibant acetate 30 mg/3 mL)

Indications: Symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older with C1-esterase-inhibitor deficiency. Dosage and administration: FIRAZYR is intended for use under the guidance and supervision of a doctor. Adults: Recommended dose is one subcutaneous injection of 30 mg for treatment of an HAE attack. Adult patients may self inject FIRAZYR under the guidance of a healthcare professional. Full contents of one syringe (3 mL) should be given slowly. Up to two further injections may be given at intervals of at least 6 hours (maximum of 3 injections in 24 hours). Adolescents and children (aged 2 to 17 years): Recommended dose is based on body weight: 12-25 kg: 10 mg (1 mL); 26-40 kg: 15 mg (1.5 mL); 41-50 kg: 20 mg (2 mL); 51-65 kg: 25 mg (2.5 mL); >65 kg: 30 mg (3 mL). No dosage regimen can be recommended in children aged <2 years or weighing <12 kg. No more than 1 injection per HAE attack was administered in the clinical trial. FIRAZYR may be administered by a healthcare professional or caregiver only after training by a healthcare professional. Hepatic or renal impairment: No dosage adjustment is required. Laryngeal symptoms: Patients with laryngeal symptoms should seek medical attention immediately after administration of FIRAZYR. Contraindications: Hypersensitivity to the active substance or to any of the excipients. Precautions: Ischaemic heart disease. Stroke. Increased systemic exposure in elderly >65 years. No data in children <2 years or <12 kg. Fertility and sexual maturation is impacted in chronic animal studies. Pregnancy Category C. May impair implantation and parturition. Breastfeeding women should not breastfeed for 12 hours after treatment. Dizziness and symptoms of an HAE attack may influence the ability to drive or use machines. Interactions: CYP450 interactions are not expected. May antagonise effects of ACE inhibitors (which should not be taken by patients with HAE). Adverse reactions: Injection site reactions (generally mild to moderate, and transient) are experienced in almost all patients. Common reactions include nausea, dizziness, headache, pyrexia, rash, pruritus, erythema, blood creatinine phosphokinase increased, prothrombin time prolonged, transaminases increased.
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