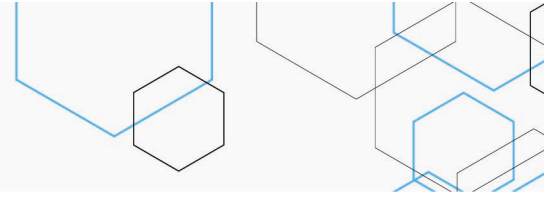


Exclusion of risedronate 5mg for the treatment of patients with Paget's disease



Technology: Risedronate 5mg tablets.

Brand name: ACTONEL® 5mg by Sanofi-Aventis.

Indication: Treatment of Paget's disease of bone.

Applicant: Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health of Brazil.

Background: Paget's disease is a chronic metabolic bone disorder characterized by highly localized areas of increased bone resorption. Risedronate is an inhibitor of bone resorption that can be used to control disease activity. The Clinical Protocol and Therapeutic Guidelines for Paget's Disease was approved by the Joint Ordinance No. 2, January 17th, 2020, which recommends the use of risedronate 35mg for the treatment of Paget's disease.

Justification for exclusion: Risedronate 5mg is not available for marketing in Brazil, and this dosage is not convenient for patients. The recommended dose is a single dose of 35mg per day, preventing patients from taking many pills a day.

Final Deliberation: The CONITEC's members present at the 89th Ordinary Meeting, on August 6th, 2020, unanimously decided to recommend the exclusion of risedronate 5mg for the treatment of Paget's disease, in the scope of the Brazilian Public Health System (SUS). The Deliberation Record No. 546/2020 was signed.

Decision: To exclude risedronate 5mg for the treatment of patients with Paget's disease, in the scope of SUS, according to Ordinance No. 35, published in the Official Gazette of the Federal Executive No. 167, Section 1, page 134, on August 31st, 2020.

