

RESTRICTED

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-62820468-000-1050301 18.03.2023 Subject: Mouth washes, gargles, lozenges and sprays containing "chlorhexidine" alone or in combination with other agents

FILE

The Clinical Assessment Unit of our Agency has reviewed mouth washes, gargles, lozenges and sprays, containing "chlorhexidine" alone or in combination with other agents. The sections on therapeutic indications, posology and additional information on special populations/pediatric population, contraindications and special precautions and warnings for use in local SmPC/PL of mouth washes, gargles, lozenges and sprays containing the aforesaid active substance must be revised to reflect the following information:

In section 4.2 Posology and Method of Administration, under the heading Posology, Frequency and Duration of Administration, include the words: "Must not be used for more than 7 consecutive days."

In the section Additional information on special populations, under the heading Pediatric Population, include the words: "-Must not be used by children aged 6 years or younger. - In children aged older than 6 years and younger than 12 years, may only be used if prescribed by a physician. - May be used by children aged 12 years or older."

In section 4.3 Contraindications, include the words "Must not be used by children aged 6 years or younger."

In section 4.4 Special precautions and warnings for use, include the words "Must not be used for more than 7 consecutive days."

Please forward any opinions, suggestions or remarks related to this decision to the Clinical Assessment Unit within 10 (ten) days after the issuing date of this announcement to unions and associations, and in the mean time, refrain from making any submissions to the Pharmacovigilance Assessment Unit and the Registration Unit regarding mouth washes, gargles, lozenges and sprays containing "chlorhexidine" alone or in combination with other agents. For your information and appropriate action. For the Agency President F. Handan Öztunca, M.Sc., Pharm. Department Head

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