

DOCUMENT

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Oral gargles, lozenges and sprays containing “chlorhexidine” alone or in combination
Association of Research-Based Pharmaceutical Companies Esentepe Mah. Büyükdere Cad.
Harman Sok. No: 4, Duran İş Merkezi, Kat: 5 34394 Şişli/İstanbul

The Clinical Assessment Unit of our Agency has reviewed oral gargles, lozenges and sprays containing “chlorhexidine” alone or in combination. In the local SmPC/PL of oral gargles, lozenges and sprays containing the aforesaid active substance, the sections on relevant therapeutic indications and posology for the pediatric population, and additional information on special populations/pediatric population, contraindications, special warnings and precautions for use should be revised to align with the following information: 4.2 Posology/Method of Administration Add the wording “Do not use for more than 7 consecutive days” in the section Posology, Frequency and Duration of Use. Additional information on special populations: Revise the section on pediatric population the read as follows: “-Do not use in children aged 6 years or younger. - Do not use this product in children older than 6 years and younger than 12 years of age, unless otherwise advised by a physician. - For use in children aged 12 years and older.” In the section 4.3. Contraindications, add the words: “Do not use in children aged 6 years or younger.” In the section 4.4 Special warnings and precautions for use, add the words: “Do not use for more than 7 consecutive days.” Any opinions, suggestions or contributions regarding this decision should be submitted to the Clinical Assessment Unit within 10 (ten) days after the issuing date of this announcement to associations and unions, and in the meantime, no submissions should be made to the Pharmacological Assessment Unit and the Marketing Authorization Unit in connection with oral gargles, lozenges and sprays containing “chlorhexidine” alone or in combination. For your information and appropriate action.

For the Agency President F. Handan Öztunca, M.Sc., Pharm. Department Head

Distribution:

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers’
Association of Türkiye Turkish Pharmaceutical Manufacturers’ Association Association of
Progressive Pharmaceutical Companies Health Products Association Pharmaceuticals, Pharmacy,
Health Sciences and Technologies Foundation

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency

Number: E-24931227-000-1245349 05.10.2023 Subject: Oral gargles, lozenges and sprays
containing “chlorhexidine” alone or in combination

FILE

The Clinical Assessment Unit of our Agency has reviewed oral gargles, lozenges and sprays containing "chlorhexidine" alone or in combination. In the local SmPC/PL of oral gargles, lozenges and sprays containing the aforesaid active substance, the sections on relevant therapeutic indications and posology for the pediatric population, and additional information on special populations/pediatric population, contraindications, special warnings and precautions for use should be revised to align with the following information: 4.2 Posology/Method of Administration Add the wording "Do not use for more than 7 consecutive days" in the section Posology, Frequency and Duration of Use. Additional information on special populations: Revise the section on pediatric population the read as follows: "-Do not use in children aged 6 years or younger. - Do not use this product in children older than 6 years and younger than 12 years of age, unless otherwise advised by a physician. - For use in children aged 12 years and older." In the section 4.3. Contraindications, add the words: "Do not use in children aged 6 years or younger." In the section 4.4 Special warnings and precautions for use, add the words: "Do not use for more than 7 consecutive days." Copies of local SmPC/PL for the aforesaid products, incorporating the changes described above, must be submitted to the Pharmacological Assessment Unit for review within 1 month after the issuing date of this announcement to associations and unions. Submissions related to products pending marketing authorization should be made to the Marketing Authorization Unit. This announcement should be regarded for products in respect to which a marketing authorization application will be submitted. Be advised not to make the submissions to the Clinical Assessment Unit. For your information and appropriate action.

Dr. Asım Hocaoglu Agency President

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers' Association of Türkiye Turkish Pharmaceutical Manufacturers' Association Association of Progressive Pharmaceutical Companies Health Products Association Pharmaceuticals, Pharmacy, Health Sciences and Technologies Foundation

Bears a secure electronic signature. Verification code:
ZW56ZW56ak1URG83M0FyM0FyZmxXZmxX Document Tracking Address:
<https://www.turkiye.gov.tr/saglik-titck-ebys>. 1 | 1