

26.02.2021 TARİHLİ SEFDİNİR İÇEREN İLAÇLAR HK_ENG

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

NORMAL 26.02.2021

No. : E-24931227-000-355846 Subject: Medicines Containing Cefdinir

DOSSIER

Ref: Association announcement dated 06.11.2018, with No. E. 192820

The referred announcement about products containing the active substance “Cefdinir” has been revoked, and it is necessary to amend as follows the relevant sections in the Summary of Product Characteristics and Package Leaflet of the medicines containing the referred active substance.

4.1 Therapeutic Indications It is indicated in the following cases in adolescents and adults: a) Community-acquired pneumonia; In the treatment of community-acquired influenza caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), b) Acute exacerbations of chronic bronchitis; In the treatment of acute bacterial exacerbations of chronic bronchitis caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), c) Acute maxillary sinusitis; In the treatment of acute maxillary sinusitis caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (caused by penicillin-susceptible strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), d) Pharyngitis/Tonsillitis; In the treatment of tonsillopharyngitis caused by group A beta-hemolytic streptococcus (*Streptococcus pyogenes*), Note: Cefdinir is effective in the eradication of *S. pyogenes* from oropharynx. Yet, cefdinir was not investigated in the prevention of rheumatic fever following *S. pyogenes* pharyngitis/tonsillitis. Only intramuscular penicillin was shown to be effective in the prevention of rheumatic fever, e) Non-complicated skin and soft tissue infections; In the treatment of non-complicated skin and soft tissue infections caused by *Staphylococcus aureus* (including beta-lactamase-producing strains) and *Streptococcus pyogenes*.

It is indicated in the following conditions in pediatric age group: a) Acute bacterial otitis media; In the treatment of acute bacterial otitis media caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (caused by penicillin-susceptible strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains),

b) Pharyngitis/Tonsillitis; In the treatment of tonsillopharyngitis caused by group A beta-hemolytic streptococcus (*Streptococcus pyogenes*), Note: Cefdinir is effective in the eradication of *S. pyogenes* from oropharynx. Yet, cefdinir was not investigated in the prevention of rheumatic fever following *S. pyogenes* pharyngitis/tonsillitis. Only intramuscular penicillin was shown to be effective in the prevention of rheumatic fever.

c) Non-complicated skin and soft tissue infections; In the treatment of non-complicated skin and soft tissue infections caused by *Staphylococcus aureus* (including beta-lactamase-producing strains) and *Streptococcus pyogenes*.

Section 4.2 Posology and Frequency of Administration

Posology/frequency and duration of administration

In infants and children older than 6 months and up to 12 years: a) In acute bacterial otitis media; 10 days and 5-10 days in cases older than 2 years at two doses of a total daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses) or at a single dose (14 mg/kg), b) In tonsillitis/pharyngitis (caused by group A streptococcus); 5-10 days at two doses of a total daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses) or for 10 days at a single dose (14 mg/kg), c) In non-complicated skin and soft tissue infections; for 10 days at two doses of a total

daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses).

It shall be used as follows in adolescents and adults: a) In community-acquired pneumonia; for 10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses), b) In the acute exacerbation of chronic bronchitis; for 5-10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or at a single dose (600 mg), c) In acute maxillary sinusitis; for at least 7-14 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or at a single dose (600 mg), d) In tonsillitis/pharyngitis (caused by group A streptococcus); for 5-10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or for 10 days at a single dose (600 mg), e) In non-complicated skin and soft tissue infections; for 10 days at two doses of a total daily dose of 600 mg/day (as 300 mg per dose in the use of two doses).

Additional Information on Special Populations: Kidney Failure: Dose adjustment is not required in people with a creatinine clearance of 30 ml/minute. In adults, it shall be administered once daily as 300 mg, if creatinine clearance is <30 ml/min. In children, it shall be administered once daily as 7 mg/kg (maximum 300 mg per day) if creatinine clearance is <30 ml/minute/1,73 m².

In adults receiving chronic hemodialysis treatment, cefdinir should be administered once every other day as 300 mg and as 7 mg/kg in children. As hemodialysis removes cefdinir from the body, a dose of 300 mg and 7 mg/kg should be administered in adults and children, respectively, after hemodialysis, and the consequent doses should be administered once every other day.

Liver Failure: Dose adjustment is not required.

Geriatric population: Dose adjustment is not required in elderly patients without kidney failure.

Pediatric Population: Cefdinir should not be administered to infants younger than 6 months.

The indication, mode of administration and dosing information related to the pediatric age group shall be removed from the SPCs and PLs of the pharmaceutical forms where dosing per kilogram cannot be performed.

Package sizes should be re-adjusted upon considering the posology section.

The SPC/PL applications for the products in which abovementioned changes are made should be submitted to the Pharmacological Evaluation Unit for review within 1 month as of the publication of this decision intended for associations, the applications for the products with ongoing registration process should be made to the Registration Unit, and this announcement should be considered for the products for which a registration application will be submitted. I hereby submit for your information and kindly request for the adoption of relevant action so that the referred applications are not made to the Clinical Evaluation Unit.

Assoc. Prof. Dr. Tolga TOLUNAY President of the Agency

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Turkish Pharmaceutical Industry Association Association of Innovator Pharmaceutical Companies Self-Care Products Association Turkish Foundation on Pharmaceuticals, Pharmacy, Health Sciences and Technologies

RESTRICTED

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency of Turkey REVOKED

NORMAL

No. : 77893119-000-E.192820 Subject: Medicines containing cefdinir
06.11.2018

DOSSIER

Ref: Association announcement dated 01.02.2018, with No. E. 22013

In line with the decision adopted by the “Clinical Evaluation Commission of Medicinal Products for Human Use” of our Agency about products containing the active substance “Cefdinir”, the referred letter has been annulled and it is necessary to amend as follows the “4.1 Therapeutic Indications” and “4.2 Posology and Method of Administration” in the Summary of Product Characteristics and the relevant sections of the Package Leaflet of the medicines containing the referred active substance.

4.1 Therapeutic Indications It is indicated in the following cases in adolescents and adults: a) Community-acquired pneumonia; In the treatment of community-acquired influenza caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), b) Acute exacerbations of chronic bronchitis; In the treatment of acute bacterial exacerbations of chronic bronchitis caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), c) Acute otitis media; In the treatment of acute otitis media caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (caused by penicillin-susceptible strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), d) Acute bacterial rhinosinusitis; In the treatment of acute bacterial rhinosinusitis caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (caused by penicillin-susceptible strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), e) Acute pharyngitis/Acute tonsillopharyngitis; In the treatment of acute tonsillopharyngitis caused by group A beta-hemolytic streptococcus (*Streptococcus pyogenes*), f) Non-complicated skin and soft tissue infections; In the treatment of non-complicated skin and soft tissue infections caused by *Staphylococcus aureus* (including beta-lactamase-producing strains) and *Streptococcus pyogenes*.

It is indicated in the following conditions in pediatric cases: a) Acute otitis media; In the treatment of acute otitis media caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (caused by penicillin-susceptible strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains),

b) Acute bacterial rhinosinusitis; In the treatment of acute bacterial rhinosinusitis caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae* (including penicillin-susceptible strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains), c) Acute pharyngitis/Acute tonsillopharyngitis; In the treatment of acute tonsillopharyngitis caused by group A beta-hemolytic streptococcus (*Streptococcus pyogenes*), d) Non-complicated skin and soft tissue infections; In the treatment of non-complicated skin and soft tissue infections caused by *Staphylococcus aureus* (including beta-lactamase-producing strains) and *Streptococcus pyogenes*.

Section 4.2 Posology and Frequency of Administration

Posology/frequency and duration of administration

In infants and children older than 6 months and up to 12 years: a) In acute otitis media; 10 days and 5-10 days in cases older than 2 years at two doses of a total daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses) or at a single dose (14 mg/kg), b) In acute bacterial rhinosinusitis; At least 10 days at two doses of a total daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses) or at a single dose (14 mg/kg), c) In acute tonsillopharyngitis/pharyngitis (caused by group A streptococcus); 5-10 days at two doses of a total daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses) or for 10 days at a single dose (14 mg/kg), d) In non-complicated skin and soft tissue infections; for 10 days at two doses of a total daily dose of 14 mg/kg/day (as 7 mg/kg per dose in the use of two doses).

It shall be used as follows in adolescents and adults: a) In acute otitis media; for 5-10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or for 5-10 days at a single dose (600 mg), b) In acute bacterial rhinosinusitis; for at least 7-14 days at two

doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or at a single dose (600 mg), c) In acute tonsillopharyngitis/pharyngitis (caused by group A streptococcus); for 5-10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or for 10 days at a single dose (600 mg), d) In non-complicated skin and soft tissue infections; for 10 days at two doses of a total daily dose of 600 mg/day (as 300 mg per dose in the use of two doses), e) In community-acquired pneumonia; for 10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses), f) In the acute exacerbation of chronic bronchiolitis; for 5-10 days at two doses of a total daily dose of 600 mg (as 300 mg per dose in the use of two doses) or at a single dose (600 mg).

The following sentences shall be added to the SPC and PL texts of the oral suspension forms; "The use of appropriate dose and pharmaceutical dosage forms is recommended for adults. Oral suspension and sachet forms may be used in patients with swallowing difficulties." The sentence reading "The use of appropriate dose and pharmaceutical dosage form is recommended in children aged between 6 months-12 years." shall be added to the SPC and PL texts of tablet, capsule and sachet forms.

Additional Information on Special Populations: Kidney Failure: Dose adjustment is not required in people with a creatinine clearance of 30 ml/minute. In adults, it shall be administered once daily if creatinine clearance is <30 ml/min. In children, it shall be administered once daily as 7 mg/kg (maximum 300 mg per day (if creatinine clearance is <30 ml/minute/1,73 m²).

In adults receiving chronic hemodialysis treatment, cefdinir should be administered once every other day as 300 mg and 7 mg/kg in children. As hemodialysis removes cefdinir from the body, a dose of 300 mg and 7 mg/kg should be administered in adults and children, respectively, after hemodialysis and the consequent doses should be administered once every other day.

Liver Failure: Dose adjustment is not required.

Geriatric population: Dose adjustment is not required in elderly patients without kidney failure.

Pediatric Population: Cefdinir should not be administered to infants younger than 6 months.

The package sizes shall also be re-adjusted upon taking into account the posology section.

I hereby submit for your information and kindly request that the SPC/PL applications for the products in which abovementioned changes are made are submitted to the Pharmacological Evaluation Unit until 03.12.2018 for review.

Dr. Hakkı GÜRSÖZ President of the Agency

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Turkish Pharmaceutical Industry Association Association of Innovator Pharmaceutical Companies Self-Care Products Association