SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
CEFDIFIX 125 mg/5 ml Powder for Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
Each 5 ml suspension contains 125 mg Cefdinir.

Excipient(s):
Contains 2105.750 mg of sucrose per 5ml suspension.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension.
Whitish-light yellow powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

In adolescents and adults:
a) Community-acquired pneumonia; In the treatment of community-acquired pneumonia caused by Haemophilus influenzae (including beta-lactamase producing strains), Streptococcus pneumoniae (caused by penicillin-susceptible strains), Moraxella catarrhalis (including beta-lactamase producing strains),
b) In acute exacerbations of chronic bronchiolitis; In the treatment of acute bacterial exacerbations of chronic bronchiolitis caused by Haemophilus influenzae (including beta-lactamase producing strains), Streptococcus pneumoniae (caused by penicillin-susceptible strains), 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 (only penicillin sensitive strains), 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 eradicating S.pyogenes from the oropharynx. However, cefdinir S.pyogenes has not been studied in the prevention of rheumatic fever after pharyngitis/tonsillitis. Only intramuscular penicillin has been shown to be effective in the prevention of rheumatic fever.
e) Uncomplicated skin and soft tissue infections; For the treatment of uncomplicated skin and soft tissue infections caused by Staphylococcus aureus (including beta-lactamase producing strains) and Streptococcus pyogenes.

In the 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-sensitive strains), Moraxella catarrhalis (including beta-lactamase producing strains),
b) Pharyngitis/Tonsillitis; In the treatment of acute tonsillopharyngitis caused by group A beta-hemolytic streptococcus (Streptococcus pyogenes),
Note: Cefdinir is effective in eradicating S.pyogenes from the oropharynx. However, cefdinir has not been studied in the prevention of rheumatic fever after S.pyogenes pharyngitis/tonsillitis. Only intramuscular penicillin has been shown to be effective in the prevention of rheumatic fever.
c) Uncomplicated skin and soft tissue infections; It is indicated for the treatment of uncomplicated skin and soft tissue infections caused by Staphylococcus aureus (including beta-lactamase producing strains) and Streptococcus pyogenes.

4.2. Posology and method of administration

Posology:

Infants and children from 6 months to 12 years:
a) In acute bacterial otitis media; A total daily dose of 14 mg/kg/day with two doses (in two doses, 7 mg/kg per dose) or as a single dose (14 mg/kg) 10 days, 5-10 days in cases older than 2 years of age,
b) In tonsillitis/pharyngitis (caused by group A streptococcus); a total daily dose of 14 mg/kg/day with two doses (in two doses, 7 mg/kg per dose) for 5-10 days or as a single dose (14 mg/kg) for 10 days,
c) In uncomplicated skin and soft tissue infections; It is used for 10 days with two doses (in two doses, 7 mg/kg per dose) with a total daily dose of 14 mg/kg/day.

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

Method of Application:
For oral use only.
CEFDIFIX can be used before or after meals.
The measuring spoon supplied with the bottle should be used to take the dose accurately.
It is recommended to use dosage and pharmaceutical dosage forms suitable for adults. Oral suspension and sachet forms can be used in patients with swallowing difficulties.

<u>Preparation of the suspension:</u>
Before preparing the suspension, the powder is loosened/aerated by inverting and shaking with the bottle closed. Boiled, cooled water is poured up to half of the marking line on the bottle and shaken well. It should be waited for 5 minutes for a homogeneous (all with similar characteristics) distribution. After this process, water is added again up to the marking line on

the bottle and shaken. The reconstituted suspension can be stored in the refrigerator at 2°-8°C for 10 days. The bottle should be shaken well before each use.

Additional information on special populations:
Kidney failure:
No dose adjustment is required in subjects with a creatinine clearance of 30 ml/min.
In adults; 300 mg once a day if creatinine clearance < 30 ml/minute
In children; If creatinine clearance is < 30 ml/min/1.73 m², 7 mg/kg (maximum 300 mg per day) is given once a day.
Cefdinir 300 mg should be given every other day in adults on chronic hemodialysis treatment, and 7 mg/kg in children. Since hemodialysis removes cefdinir from the body, a dose of 300 mg in adults and 7 mg/kg in children should be given after each hemodialysis, and the next doses should be continued every other day.

Liver failure:
No dose adjustment is required.

Geriatric population:
No dosage adjustment is required in elderly patients without renal impairment.

Pediatric population:
Cefdinir should not be given to infants younger than 6 months old.

4.3. Contraindications
Cefdinir is contraindicated in patients with hypersensitivity to cephalosporin group antibiotics.

4.4. Special warnings and precautions for use

Before starting cefdinir treatment, the patient should be investigated for hypersensitivity to cefdinir, other cephalosporins, penicillins or other drugs. If cefdinir treatment is to be started in patients with penicillin allergy, care must be taken. If an allergic reaction to cefdinir occurs, drug therapy should be discontinued. Serious acute hypersensitivity reaction may require treatment with epinephrine, intravenous fluid administration, intravenous antihistamines, corticosteroids, pressor amines, and airway opening with oxygen administration.

Clostridium difficile associated diarrhea (CDAD) has been reported with all antibacterial agents such as CEFDIFIX and can range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents disrupts the normal flora of the intestine and causes C. difficile to form.

C. difficile produces toxins A and B that cause CDAD. Hypertoxin producing strains of C.difficile cause increased morbidity and mortality. These infections may be resistant to antimicrobial therapy and require colectomy. CDAD should be considered in patients who develop diarrhea after antibiotic use. The medical history of the patient who has been reported to develop CDAD more than two weeks after the use of antibacterial agents is required.

If it is suspected or confirmed that CDAD has occurred, continued antibiotic therapy is not used directly against C. difficile and treatment may not be continued.

Like other broad-spectrum antibiotics, caution should be exercised when administering cefdinir to people with a history of colitis.

In patients with transient or resistant renal impairment (creatinine clearance <30 mL/min), the total daily dose of cefdinir should be reduced, since the recommended dose of high and prolonged plasma concentration of cefdinir may be followed.

Since combined treatment with cephalosporins and aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics (or: furosemide) may cause renal impairment, renal functions should be carefully monitored in such treatments. Patients with impaired renal function should be closely monitored.

CEFDIFIX contains sucrose as an excipient. Patients with rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5. Interaction with other medicinal products and other forms of interaction

Concomitant use:
Potential nephrotoxic substances (such as aminoglycoside antibiotics, colistin, polymyxin B, viomycin) and potent diuretics (such as ethacrynic acid, furosemide) cause an increase in renal dysfunction.

Antacids:
Concomitant use of 300 mg of cefdinir with antacids containing aluminium or magnesium reduces C_{max} and absorption rate by approximately 40%. The time to reach C_{max} is 1 hour. There is no significant effect on cefdinir pharmacokinetics when antacid is taken 2 hours before or after cefdinir ingestion. If antacids need to be taken during cefdinir use, antacids should be taken at least 2 hours before or after cefdinir intake.

Probenecid:
Like other beta-lactam antibiotics, probenecid inhibits the renal excretion of cefdinir, doubling its AUC, increasing peak plasma cefdinir levels by 54%, and prolonging the apparent elimination half-life by 50%.

Medicines containing iron or foods containing iron:
When cefdinir is taken with a therapeutic iron supplement containing 60 mg of essential iron or vitamins containing 10 mg of essential iron, the absorption of cefdinir is reduced by 80% and 31%, respectively. If probenecid needs to be taken while using cefdinir, it should be taken at least 2 hours before or after taking cefdinir.

The effect of essential iron-containing foods (iron-containing oils for breakfast) on cefdinir has not been studied.

Faeces of individuals taking cefdinir have been reported to be reddish in color. In the majority of cases, patients received products containing iron. The red color is due to the combination of cefdinir and cefdinir broken down products in the intestine and the inability to absorb iron.

Lab interactions:
While false positive results may occur in the tests performed to search for ketones in the urine using nitroprusside, false positive results do not occur in the tests using nitroferricyanide.

Urine glucose measurement using cefdinir therapy, Benedict's solution or Fehling's solution may cause false positive reactions. It is recommended to use glucose tests based on enzymatic glucose oxidase enzyme.
Cephalosporins usually induce a positive direct Coombs test.

Additional information on special populations
There are no data.

Paediatric population
There are no data.

4.6 Fertility, pregnancy and lactation

General advice
Pregnancy category: B

Women of childbearing potential / Birth control (Contraception)

There is no warning for the use of the drug in women of childbearing potential and those using birth control (contraception).

Pregnancy
No clinical data are available for cefdinir in pregnancy.
Animal studies do not confirm direct or indirect harmful effects with respect to pregnancy / embryonal / fetal development / parturition or postnatal development.
Caution should be exercised when administered to pregnant women.

Breast-feeding
Cefdinir has not been found to be found in human milk following administration of a single 600 mg dose.
Cefdinir is not excreted in breast milk.

Fertility
It has no known effect on fertility.

4.7. Effects on ability to drive and use machines
It has no effect on the ability to drive and use machines.

4.8. Undesirable effects

The safety profile of cefdinir (600 mg/day) is based on data from clinical studies with 3841 adult and adolescent patients. Most of the side effects seen are mild and limited. No deaths or permanent disabilities have been associated with cefdinir.
Adverse drug reactions are listed according to the frequency defined below:

Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

Infections and infestations
Uncommon: Moniliasis

Nervous system diseases
Common: Headache
Uncommon: insomnia, somnolence, dizziness

Gastrointestinal diseases
Common: Abdominal pain, nausea, diarrhea
Uncommon: flatulence, vomiting, indigestion, constipation, abnormal stool

Skin and subcutaneous tissue diseases
Uncommon: Skin rash, pruritus.

Pregnancy, pueperium states and perinatal diseases
Common: Vaginitis (in women), vaginal moniliasis (in women)
Uncommon: leukorrhea (female)

General disorders and administration site conditions
Uncommon: Fatigue, dry mouth, decreased appetite

Studies
In studies conducted with cefdinir in the USA, changes in laboratory tests have been reported regardless of its relationship with cefdinir.

Common: Urine protein increased, urinary leukocyte cells increased, gamma-glutamyl transferase (GGT) increased, lymphocyte count increased or decreased, microhematuria increased.

Uncommon: Increase or decrease in glucose levels, increase in urine glucose levels, increase and decrease in white blood cells, increase in liver values (AST, ALT, alkaline phosphatase), increase in eosinophils, increase or decrease in phosphorus levels, decrease in bicarbonate levels, blood urea nitrogen (BUN) level, decrease in hemoglobin level, increase and decrease in polymorphonuclear neutrophil (PMNs) level, increase in bilirubin levels, increase in lactate dehydrogenase level, increase in platelets, increase in potassium level, increase in urine pH, increase in urea density.

Post marketing
Adverse events and changes in laboratory tests were reported in Japan in 1991, regardless of the relationship of cefdinir post-marketing to cefdinir; shock, rare death with anaphylaxis, facial and laryngeal edema, suffocation (serum disease reactions), conjunctivitis, stomatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, acute hepatitis, cholestasis, fulminate hepatitis, hepatic failure, jaundice, amylase increased, acute enterocolitis, bloody diarrhoea, hemorrhagic colitis, melena, pseudomembranous colitis, pancytopenia, granulocytopenia, leukopenia, thrombocytopenia, idiopathic thrombocytopenic purpura, hemolytic anemia, acute respiratory failure, asthma attack, drug-induced pneumonia, pneumonia , idiopathic interstitial pneumonia, fever, acute renal failure, nephropathy, bleeding tendency, coagulation disorder, diffuse intravascular coagulation, upper GI bleeding, peptic ulcer, ileus, unconsciousness, allergic

vasculitis, possible cefdinir-diclofenac interaction, heart failure, chest pain, myocardial infarction, hypertension, rhabdomyolysis and involuntary movements.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continuous monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Turkish Pharmacovigilance Center (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr ; Tel: 0 800 314 0008; Fax: 0 312 218 35 99)

4.9. Overdose and treatment

There is no information on overdose of cefdinir in humans. In acute toxicity studies in rodents, a single oral dose of 5600 mg/kg did not cause adverse effects.

Symptoms following overdose of other beta-lactam antibiotics are nausea, vomiting, epigastric pain, diarrhea and convulsions.

Cefdinir is removed from the body by hemodialysis.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Systemic antibacterials, third generation cephalosporins
ATC code: J01DD15

As with other cephalosporins, the bactericidal activity of cefdinir is mediated by inhibition of cell wall synthesis. Cefdinir is stable in the presence of certain beta-lactamase enzymes.

Consequently, many organisms resistant to penicillins and some cephalosporins are susceptible to cefdinir.
Cefdinir has been shown to be effective on many strains of the following microorganisms:

Aerobic Gram-Positive Microorganisms:
Staphylococcus aureus (including beta-lactamase producing strains)
Note: Cefdinir is inactive against methicillin-resistant staphylococci.
Streptococcus pneumoniae (penicillin-susceptible strains only)
Streptococcus pyogenes
Staphylococcus epidermidis (methicillin-susceptible strains only)
Streptococcus agalactiae
Viridans group streptococci
Note: Cefdinir is inactive against Enterococcus and methicillin-resistant Staphylococcus strains.

Aerobic Gram-Negative Microorganisms:
Haemophilus influenzae (including beta-lactamase producing strains)
Haemophilus parainfluenzae (including beta-lactamase producing strains)
Moraxella catarrhalis (including beta-lactamase producing strains)

Citrobacter diversus
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Note: Cefdinir is inactive against Pseudomonas and Enterobacter species.

5.2. Pharmacokinetic properties

General proporties

Cefdinir can maintain its highest concentration in the blood for 1.8 hours. Although the level of drug in the blood decreases afterwards, the effect on bacteria can continue for 18-26 hours thanks to its high (70%) binding to plasma proteins. Cefdinir is in the group of antibiotics that shows its effect not dependent on time, but on dose. For this reason, reaching a high blood value once a day is sufficient for the effect to last for 24 hours.

Absorption:

Cefdinir reaches peak plasma concentrations 2-4 hours after oral administration. The estimated absolute bioavailability of cefdinir suspension is 25%. Cefdinir can be taken before or after meals.

The mean cefdinir plasma concentrations and pharmacokinetic values obtained after a single dose administration of cefdinir suspension to children aged 6 months to 12 years are given in the table below.

Dose	**C_{maks} (µg/mL)**	**t_{maks} (sa)**	**EAA (µg-sa/mL)**
7 mg/kg	2,30 (± 0,65)	2,2 (± 0,6)	8,31 (± 2,50)
14 mg/kg	3,86 (± 0,62)	1,8 (± 0,4)	13,4 (± 2,64)

Multiple dose administration; Cefdinir does not accumulate in plasma with once or twice daily administration in patients with normal renal function.

Distribution:
The mean volume of distribution (Vd) of cefdinir in adults is 0.35 L/kg (±0.29). The volume of distribution of cefdinir in the pediatric population (6 months-12 years) is 0.67L/kg (±0.38). Cefdinir is 60% to 70% bound to plasma proteins in adults and children. Binding is independent of concentration.

Skin vesicle:
Median maximal vesicle fluid concentrations at 4 to 5 hours following 300 mg and 600 mg cefdinir ingestion in adults are 0.65 (0.33 vs 1.1) and 1.1 mcg/mL (0.49 vs 1.9), respectively. Mean vesicle C_{max} and AUC values were 48% (± 13) and 91% (± 18) of the corresponding plasma values.

Tonsil tissue:
In adult patients undergoing elective tonsillectomy, the median tonsil tissue cefdinir concentration was 0.25 (0.22 to 0.46) and 0.36 mcg/mL (0.22 to 0.80) at 4 hours following

ingestion of 300 mg and 600 mg cefdinir, and the mean sinus tissue concentration was greater than the plasma concentration.
It was found to be equivalent to 24% (±8).

Sinus tissue:
In adult patients with elective maxillary and ethmoid sinus surgery, the median sinus tissue cefdinir concentration is <0.12 (<0.12 to 0.46) and <0.21 (0.12 to 2.0) mcg/mL at 4 hours following ingestion of 300 and 600 mg of cefdinir, respectively. The mean tonsil tissue concentration was equivalent to 16% (±20) of the plasma concentration.

Lung tissue:
In adult patients undergoing diagnostic bronchoscopy, median bronchial mucosa cefdinir concentrations were 0.78 (<0.06 to 1.33) and 1.14 (<0.06 to 1.92) mcg/mL and plasma concentrations were 31% (±18) 4 hours after 300 mg and 600 mg cefdinir ingestion, respectively. is Retrospective median epithelial layer fluid concentrations were 0.29 (<0.3 to 4.73) and 0.49 (<0.3 to 0.59), respectively, and the plasma concentration was 35% (±83).

Middle ear fluid:
Mean concentrations in middle ear fluid 3 hours after a single dose of 7 mg/kg and 14 mg/kg cefdinir administration to pediatric patients with acute bacterial otitis media are 0.21 (< 009-0.94) and 0.72 (0.14-1.42) µg, respectively. /ml. The mean middle ear fluid concentrations are above the corresponding plasma concentrations. It was determined as 15% (± 15).

Cerebrospinal Fluid:
There are no data on the penetration of cefdinir into the cerebrospinal fluid.

Biotransformation:
Cefdinir is not metabolized efficiently. Activity is primarily due to the parent drug. Cefdinir is excreted primarily by the renal route unchanged, with a mean t1/2 of 1.7 (±0.6 h).

Elimination:
In healthy subjects with normal renal function, renal clearance is 2.0 (±1.0) mL/min/kg. The apparent oral clearance following ingestion of 300 and 600 mg doses is 11.6 (±6.0) and 15.5 (±5.4) mL/min/kg. The amount excreted unchanged in the urine after 300 and 600 mg doses was 18.4% (± 6.4) and 11.6% (± 4.6), respectively.

Linearity/Non-linearity:
The pharmacokinetics of cefdinir are linear and dose-independent in humans at oral doses of 200-400 mg.

The characteristic properties of the patients

Kidney failure:
In a study of 21 subjects with varying degrees of renal function, significant decreases in oral and renal clearance of cefdinir were approximately proportional to decreases in creatinine clearance (CLCR). Compared with patients with normal renal function, plasma cefdinir concentration remains high and prolonged in patients with renal impairment. In people with CLCR < 30 mL/min, C_{max} increases ~ 2 times, tl/2 ~ 5 times, and AUC increases 6 times.

Dose adjustment is recommended in patients with significant severe renal impairment (creatinine clearance < 30 mL/min).

Hemodialysis:
According to the cefdinir pharmacokinetic data of 8 adult patients undergoing hemodialysis, it was reported that dialysis removed cefdinir from the body by 63% and it reduced tl/2 of the apparent elimination from 16 hours to 3.2 hours. Dose adjustment should be made in this patient population.

Liver failure:
Pharmacokinetic studies of cefdinir have not been conducted in patients with hepatic impairment, as cefdinir is mostly eliminated by the kidneys and is not metabolised efficiently. No dose adjustment is required in this patient population.

In geriatric patients:
The effect of age on the pharmacokinetics of cefdinir was studied in 32 subjects aged 19-91 years after a single 300 mg dose of cefdinir. In elderly subjects (N=16) systematically exposed to cefdinir, C_{max} was increased by 44% and AUC by 86%. This increase is due to the decreased clearance of cefdinir. No discernible change in apparent elimination t 1/2 was observed due to the reduction in the apparent volume of distribution (2.2 ± 0.6 hours in the elderly versus 1.8 ± 0.4 hours in the young). Since clearance of cefdinir appears to be primarily related to change in renal function rather than age, no dose adjustment is required in elderly patients without severe renal impairment.

Gender and race:
The results of the clinical pharmacokinetic meta-analysis (N=217) showed that gender and race had no significant effect on the pharmacokinetics of cefdinir.

5.3. Preclinical safety data
The carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in V79 Chinese hamster lung cells in the bacterial reverse mutation assay (Ames) or the point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase (HGPRT) site. No clastogenic effects were observed in V79 Chinese hamster lung cells in in vitro structural chromosome aberration assay or in vivo mouse bone marrow micronucleus assay. Fertility and reproductive performance were not affected in rats at oral doses up to 1000 mg/kg/day (70 times the human dose on a mg/kg/day basis, 11 times the human dose on a mg/m2/day basis).

Oral doses up to 1000 mg/kg/day (70 times the human dose on a mg/kg/day basis, 11 times the mg/m2/day) in rats or 10 mg/kg/day (human dose on a mg/kg/day basis) in rabbits Cefdinir was not teratogenic at oral doses up to 0.7 times, 0.23 times on a mg/m2/day basis. Maternal toxicity (reduced weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day with no adverse effects in the offspring. Decreased body weight was observed at ≥100 mg/kg/day in rat fetuses and ≥32 mg/kg/day in rat progeny.

No effects on maternal reproductive parameters, progeny survival, development, behavior or reproductive function were observed.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sucrose
Xanthan Gum
Sodium Benzoate
Trisodium Citrate Dihydrate
Citric Acid (Anhydrous)
Magnesium Stearate
Colloidal Silicon (Anhydrous)
Strawberry flavor

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
24 months.

6.4. Special precautions for storage
Store in powder form below 25 °C, at room temperature. After reconstitution, it should be stored in the refrigerator for a maximum of 10 days.

6.5 Nature and contents of container
It is presented in a cardboard box with a 125 cc engraved amber colored bottle with a sealed lid, containing 100 ml of powder that gives an oral suspension after reconstitution, a 5 ml scale plastic spoon as a scale, and instructions for use.

6.6. Special precautions for disposal and other handling
Unused products or waste materials should be disposed in accordance with the "Regulation for the Control of Medical Wastes" and the "Regulation for the Control of Packages and Package Wastes".

7. MARKETING AUTHORISATION HOLDER
Humanis Saglik A.S.
Mahmutbey Mah. Tasocagi Yolu Caddesi Solen Residance Apt. No:19/1/11
Bagcilar-Istanbul/TURKEY

8. MARKETING AUTHORISATION NUMBER(S)
2018/471

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorisation: 06.09.2018
Date of renewal of the authorisation:

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