17-10-2022
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210mm

Sedil™ Tablets / Oral Solution
(Cetirizine Dihydrochloride)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Sedil™ 10mg Film Coated Tablets
Each film coated tablet contains:
Cetirizine Dihydrochloride Ph. Eur....10mg

Sedil™ Oral Solution
Each 5ml contains:
Cetirizine Dihydrochloride Ph. Eur.....5mg

PHARMACEUTICAL FORM
Tablet / Oral Solution

CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS:
In adults and paediatric patients 6 years and above:
- Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria.

POSOLOGY AND METHOD OF ADMINISTRATION:
Posology:
Tablets:
Adults and adolescents over 12 years of age: Recommended dose is 10mg once daily. A 5mg starting dose (1 half tablet) may be proposed if this leads to satisfactory control of the symptoms.
Children aged 6 to 12 years: 5mg twice daily (a half tablet twice daily).
Adolescents above 12 years: 10mg once daily (1 tablet). A 5mg starting dose (a half tablet) may be proposed if this leads to satisfactory control of the symptoms.

Oral Solution:
Adults and children 6 years and above: 10mg daily.
Adults and children aged 12 years and above: 10ml once daily.
Children aged between 6 to 11 years: Either 5ml twice daily or 10ml once daily.
Children aged between 2-5 years: 5mg daily. Either 5ml once daily or 2.5ml twice daily.
Insufficient clinical data to recommend the use of cetirizine in children under 2 years of age.
Elderly subjects: There is no data to suggest that the dose should be reduced in elderly patients, provided that the renal function is normal.

Special Population:
Elderly: The dose needs to be reduced in elderly subjects provided that the renal function is normal.
Renal impairment: The dosing intervals must be individualized according to renal function. Dosing adjustments for adult patients with impaired renal function.

Group	Creatinine clearance (ml/min)	Posology and frequency
Normal	≥80	10mg once daily
Mild	50-79	10mg once daily
Moderate	30-49	5mg once daily
Severe	< 30	5mg once every 2 days
End-stage renal disease – Patients undergoing dialysis	< 10	Contraindicated

In paediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance, age and body weight of the patient.
Hepatic impairment: No dose adjustment is needed in patients with hepatic impairment.
Patients with hepatic impairment and renal impairment: Dose adjustment is recommended.

Method of administration:
For oral use only.
The tablets need to be swallowed with a glass of liquid.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or hydroxyzine or to any piperazine derivatives.
Patients with severe renal impairment at less than 10ml/min creatinine clearance.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
- Precaution is recommended if alcohol is taken concomitantly.
- Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.
- Caution in epileptic patients and patients at risk of convulsions is recommended.
- Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.
- Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
- Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

Paediatric population:
The use of the film-coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation. It is recommended to use a paediatric formulation (oral solution) of cetirizine. Cetirizine oral solution is not recommended in children aged less than 2 years.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400mg/day).
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.
In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance, although cetirizine does not potentiate the effect of alcohol (0.5g/l blood levels).

FERTILITY, PREGNANCY AND LACTATION:
Fertility: Limited data is available on human fertility but no safety concern has been identified. Animal data show no safety concern for human reproduction.
Pregnancy: Caution should be exercised when prescribing to pregnant women.
Breast-feeding: Cetirizine is excreted in human milk at concentrations representing 25% to 90% of those measured in plasma, depending on sampling time after administration. Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, caution should be exercised when prescribing cetirizine to lactating women.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
Patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery. They should not exceed the recommended dose and should take their response to the medicinal product into account.
In sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

UNDESIRABLE EFFECTS:
Clinical studies have shown that cetirizine at the recommended dosage has minor adverse effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported. Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine dihydrochloride.

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Post-marketing experience: Frequencies are defined as follows: 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), not known (cannot be estimated from the available data).
Blood and lymphatic system disorders: ***Very rare:*** Thrombocytopenia.
Immune system disorders: ***Rare:*** Hypersensitivity. ***Very rare:*** Anaphylactic shock.
Metabolism and nutrition disorders: ***Not known:*** Increased appetite.
Psychiatric disorders: ***Uncommon:*** Agitation. ***Rare:*** Aggression, confusion, depression, hallucination, insomnia. ***Very rare:*** Tics. ***Not known:*** Suicidal ideation, nightmare.
Nervous system disorders: ***Uncommon:*** Paraesthesia. ***Rare:*** Convulsions. ***Very rare:*** Syncope, dysgeusia, tremor, dystonia, dyskinesia. ***Not known:*** Amnesia, memory impairment.
Eye disorders: ***Very rare:*** Accommodation disorder, blurred vision, oculogyration.
Ear and labyrinth disorders: ***Not known:*** Vertigo.
Cardiac disorders: ***Rare:*** Tachycardia.
Gastrointestinal disorders: ***Uncommon:*** Diarrhoea.
Hepatobiliary disorders: ***Rare:*** Abnormal hepatic function (increased transaminases, alkaline phosphatase, gamma-GT and bilirubin). ***Not known:*** Hepatitis.
Skin and subcutaneous tissue disorders: ***Uncommon:*** Rash, pruritus. ***Rare:*** Urticaria. ***Very rare:*** Angioneurotic oedema, fixed drug eruption. ***Not known:*** Acute generalized exanthematous pustulosis.
Musculoskeletal and connective tissue disorders: ***Not known:*** Arthralgia.
Renal and urinary disorders: ***Very rare:*** Dysuria, enuresis. ***Not known:*** Urinary retention.
General disorders and administration site conditions: ***Uncommon:*** Asthenia, malaise. ***Rare:*** Oedema.
Investigations: ***Rare:*** Weight increased.
Description of selected adverse reactions: After discontinuation of cetirizine, pruritus (intense itching) and/or urticaria have been reported.

OVERDOSE:
There is no known specific antidote to cetirizine. If overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage may be considered shortly after ingestion of the drug. Cetirizine is not effectively removed by haemodialysis.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Antihistamine for systemic use, piperazine derivatives. **ATC code:** R06A E07.
Mechanism of action: Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H_1-receptors. In vitro receptor binding studies have shown no measurable affinity for other than H_1-receptors.
Pharmacodynamic effects: In addition to its anti-H_1 effect, cetirizine was shown to display anti-allergic activities: at a dose of 10mg once or twice daily, it inhibits the late phase recruitment of eosinophils, in the skin and conjunctiva of atopic subjects submitted to allergen challenge.

PHARMACOKINETIC PROPERTIES:
Absorption: The steady-state peak plasma concentrations is approximately 300ng/mL and is achieved within 1.0 ± 0.5 hour. The distribution of pharmacokinetic parameters such as peak plasma concentration (C_{max}) and area under curve (AUC), is unimodal. The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased. The extent of bioavailability is similar when cetirizine is given as solutions or tablets.
Distribution: The apparent volume of distribution is 0.50 l/kg. Plasma protein binding of cetirizine is 93 ± 0.3%. Cetirizine does not modify the protein binding of warfarin.
Biotransformation: Cetirizine does not undergo extensive first pass metabolism.
Elimination: About two third of the dose are excreted unchanged in urine. The terminal half-life is approximately 10 hours and no accumulation is observed for cetirizine following daily doses of 10mg for 10 days.
Linearity/non-linearity: Cetirizine exhibits linear kinetics over the range of 5 to 60mg.

Special populations:
Elderly: The decrease in cetirizine clearance in these elderly volunteers appeared to be related to their decreased renal function.
Paediatric population: The half-life of cetirizine was about 6 hours in children of 6-12 years and 5 hours in children 2-6 years. In infants and toddlers aged 6 to 24 months, it is reduced to 3.1 hours.
Renal impairment: Dosing adjustment is necessary in patients with moderate or severe renal impairment.
Hepatic impairment: Dosing adjustment is only necessary in patients with hepatic impairment if concomitant renal impairment is present.

SHELF LIFE
See expiry on the pack

AVAILABILITY
Sedil™ 10mg film coated tablets in a pack of 30`s
Sedil™ oral solution in a pack of 120ml

INSTRUCTIONS
Dosage: As advised by the physician.
To be sold on the prescription of a registered medical practitioner only.
Keep out of the reach of children.
For Tablets: Avoid exposure to heat, light and humidity. Store between 15 to 30°C.
For Oral Solution: Do not store over 30°C, and protect from heat, light and freezing.

Improper storage may deteriorate the medicine.

For Oral Solution: Medicine should not be used if container is leaking or it contains undissolved particle(s).

سیـــڈل ٹیبلٹ/اورل سلوشن

(سیٹریزن ڈائی ہائیڈروکلورائیڈ)

ہدایات: خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔
برائے ٹیبلٹ: دوا کو گرمی، روشنی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری
سینٹی گریڈ کے درمیان میں رکھیں۔
برائے اورل سلوشن: دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں،
گرمی، روشنی اور منجمد ہونے سے محفوظ رکھیں۔
ورنہ دوا خراب ہو جائیگی۔
برائے اورل سلوشن: دوا کے لیک ہونے، یا اس میں کوئی غیر حل پزیر شے
نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

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