

SPMC Cetirizine Tablets BP 10mg

PRESENTATION:

Cetirizine BP tablets 10mg, Bulk pack -1000 tablets, Blister packs - 200 tablets (20x10)

Each white, circular, bi convex film coated tablets of 8.0mm diameter with "SPC" or "SPMC" letters on one side and score mark on the reverse contains Cetirizine Hydrochloride BP 10mg.

DESCRIPTION:

Cetirizine is a non-sedative (newer) class of antihistamine. That is used in various kinds of allergies. It is safe and effective in adults and children. Cetirizine binds to the Histamine 1 (H 1) receptor and block the action of histamine on H1 receptor. This helps prevent the dilation of the vessels, thus reducing the redness and swelling.

INDICATIONS AND DOSE:

Symptomatic relief of allergy such as hay fever, chronic

Idiopathic urticaria, atopic dermatiti

Child: 2–5 years: 2.5 mg twice daily, 6–11 years: 5mg twice daily, 12–17 years: 10 mg once daily

Adult: 10 mg once daily

SIDE EFFECTS:

Uncommon

Agitation. Asthenia. Diarrhea. Malaise. Paraesthesia. Skin reactions

Rare or very rare

Aggression. Angioedema. Confusion. Depression. Hallucination. Hepatic function abnormal. Insomnia. Movement disorders. oculogyration. Oedema. Seizure. Syncope. Tachycardia. Taste altered. Thrombocytopenia. Tic. Tremor. Urinary disorders. Vision disorders. Weight increased

Frequency not known

abdominal pain. Appetite increased. Dizziness. Drowsiness. Dry mouth. Headache. Memory Loss. Nausea. Pharyngitis. Suicidal ideation. Vertigo.

SIDE-EFFECTS, FURTHER INFORMATION

Non-sedating antihistamines such as cetirizine hydrochloride cause less sedation and psychomotor impairment than the older antihistamines, but can still occur; sedation is generally minimal. This is because non-sedating antihistamines penetrate the blood brain barrier to a much lesser extent.

PATIENT AND CARER ADVICE:

Medicines for Children leaflet: Cetirizine hydrochloride for hay fever Driving and skilled tasks although drowsiness is rare, nevertheless patients should be advised that it can occur and may affect performance of skilled tasks (e.g. cycling or driving); alcohol should be avoided.

RENAL IMPAIRMENT:

Adults Avoid if eGFR less than 10 mL/minute/1.73m².

Children Avoid if estimated glomerular filtration rate less than 10 mL/minute/1.73m².

Dose adjustments in adults Use half normal dose if eGFR 30–50

mL/minute/1.73m². Use half normal dose and reduce dose frequency to alternate days if eGFR10–30 mL/minute/1.73m². **In children** Use half normal dose if estimated glomerular filtration rate 30–50 mL/minute/1.73m². Use half normal dose and reduce dose frequency to alternate days if estimated glomerular filtration

rate 10-30 mL/minute/1.73m².

CAUTIONS:

Epilepsy, Patients with increased risk of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia), epileptic patients and patients at risk of convulsions. Hepatic and mild to moderate renal impairment. Children. Pregnancy and lactation

CONTRAINDICATION:

Severe renal impairment

PREGNANCY:

Advice to avoiding antihistamines their use during pregnancy; however, there is no evidence of teratogenicity.

BREAST FEEDING:

Most antihistamines are present in breast milk in varying amounts; although not known to be harmful, advice avoiding their use in mothers who are breastfeeding.

DRUG INTERACTIONS:

Cetirizine increased the risk of antimuscarinic side effects when given antihistamines given with anti-muscarinic. Plasma concentration of non-sedative antihistamines is possibly increased by ritonavir (anti-viral). Antihistamines increased risk of ventricular arrhythmias when given with sotalol. Additive CNS depression when administered concomitantly with other CNS depressants (e.g. sedatives, tranquilizers).

DRIVING AND SKILLED TASKS:

Although drowsiness is rare, nevertheless, patients should be advised that it can occur and may affect performance of skilled tasks (e.g. cycling or driving); alcohol should be avoided.

OVERDOSAGE:

Symptoms: Confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, urinary retention. Management: Symptomatic and supportive treatment. Gastric lavage may be performed following early ingestion.

STORAGE:

Keep tightly closed in a dry place at a temperature not exceeding 30 0 C. Keep all the medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing
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