METAPHARMACEUTICAL IND SL
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Technical Data sheet

CETIRIZINA DIHIDROCLORURO Ph.Eur.		
DESCRIPTION DCI: CETIRIZINE DIHYDROCHLORIDE	DESCRIPTION DOE: CETIRIZINA DIHIDROCLORURO	
CAS Nº: 83881-52-1	EC Nº: 620-533-8	AEMPS CODE: 2364DH
MOL. WEIGHT: 461.8	MOL. FORMULA:: C21H27Cl3N2O3	ARTICLE CODE: 151231

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Freely soluble in water, practically insoluble in acetone and in methylene chloride
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7
pH	1.2 - 1.8
Related substances	
Impurity A	=< 0.15 %
Impurity B	=< 0.15 %
Impurity C	=< 0.15 %
Impurity D	=< 0.15 %
Impurity E	=< 0.15 %
Impurity F	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.3 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.2 %
Assay	99.0 - 101.0 %
Residual solvents	
Acetone	=< 1000 ppm
Particle size	
d (0.5)	In-house limits
d (0.9)	In-house limits

COMPLIES WITH

European Pharmacopoeia 9.0

STORAGE

Keep in a tightly closed container, in a cool and a dry place protected from light.

REMARKS

Properties
It is a selective H1 antihistamine that lacks anticholinergic action and does not cross the blood-brain barrier (BBB) so it has little sedative effect at the usual recommended doses. Long half-life (more suitable in prescribed treatment than on demand). Start of action faster than others in the group.

Clinical Use
In pediatric patients from 2 years for the treatment of seasonal and perennial allergic rhinoconjunctivitis and / or chronic urticaria. Not recommended for children under 2 years.

Contraindications
Hypersensitivity to cetirizine, hydroxyzine or other piperazine derivative.
Patients with severe renal insufficiency with renal clearance lower than 10 ml / min.
Some of the presentations marketed as tablets contain lactose. Patients with rare hereditary problems of galactose

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intolerance, Lapp lactase deficiency (failure observed in certain populations of Lapland) or glucose or galactose malabsorption should not take this medicine.

Precautions
Avoid alcohol and sedatives. Inhibit the allergy skin test, spacing 3 days. Caution is advised in epileptic patients and patients at risk of seizures. Some oral drops may cause allergic reactions (possibly delayed), because it contains methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216).

Side effects
Drowsiness, dry mouth, headache, dizziness, fatigue, gastrointestinal discomfort, rhinitis, respiratory, mediastinal and thoracic disorders.

Drug interactions
No significant pharmacodynamic or pharmacokinetic interactions have been reported in the drug-drug interaction studies developed.