METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

010294-TDS-ENG-2023

CETIRIZINA DIHIDROCLORURO (EUR. PH.)		
DESCRIPTION DCI: CETIRIZINE DIHYDROCHLORIDE	DESCRIPTION DOE: CETIRIZINA DIHIDROCLORURO	
CAS Nº: 83881-52-1	EC Nº: 620-533-8	AEMPS CODE: 2364DH
MOL. WEIGHT: 461.81	MOL. FORMULA: C21H27Cl3N2O3	ARTICLE CODE: 010294

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 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Cetirizine Dihydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

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).

TECHNICAL DATA SHEET

010294-TDS-ENG-2023

CETIRIZINA DIHIDROCLORURO (EUR. PH.)		
DESCRIPTION DCI: CETIRIZINE DIHYDROCHLORIDE	DESCRIPTION DOE: CETIRIZINA DIHIDROCLORURO	
CAS Nº: 83881-52-1	EC Nº: 620-533-8	AEMPS CODE: 2364DH
MOL. WEIGHT: 461.81	MOL. FORMULA: C21H27Cl3N2O3	ARTICLE CODE: 010294

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 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.

Formulation examples

5 mL Syrup - CETIRIZINA DIHYDROCHLORIDE 1mg/mL

CETIRIZINE DIHYDROCHLORIDE - **0.1 g**
Liquid Maltitiol - **35 g**
Sodium citrate dihydrate - **0.1 g**
Propylene glycol - **6 g**
Methylparaben - **0.09 g**
Propilparaben - **0.01 g**
Saccharin sodium - **0.075 g**
Raspberry aroma - **0.2 mL**
Purified water - **100 mL**