METAPHARMACEUTICAL IND SL
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Technical Data sheet

FLUOXETINA HCL (PH.EUR)		
DESCRIPTION DCI: FLUOXETINE HYDROCHLORIDE		DESCRIPTION DOE: FLUOXETINA HIDROCLORURO
CAS Nº: 56296-78-7	EC Nº: 260-101-2	AEMPS CODE: 2331CH
MOL. WEIGHT: 345.83	MOL. FORMULA:: C17H19CIF3NO	ARTICLE CODE: 0979

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Sparingly soluble in water, freely soluble in methanol, sparingly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
pH	4.5 - 6.5
Optical rotation	-0.05º / +0.05º
Related substances	
Impurity C	=< 0.15 %
Impurity A	=< 0.25 %
Impurity B	=< 0.25 %
Unspecified impurities	=< 0.10 %
Total of impurities	=< 0.5 %
Acetonitrile	=< 0.1 %
Water	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %
Residual solvents	
Toluene	=< 100 ppm
Methanol	=< 200 ppm
Methylethylketone	=< 1500 ppm
Ethyl acetate	=< 200 ppm

COMPLIES WITH

European Pharmacopoeia 9.0

STORAGE

Store in a cool, well-ventilated area, away from sources of heat, flames, sparks and other sources of ignition.

REMARKS

Fluoxetine HCl is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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

Properties and uses
Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) derived from phenylpropanolamine. It is easily absorbed in the digestive tract, reaching maximum concentrations at 6 - 8 h. The degree of binding to plasma proteins is 95%. It is widely distributed. It is metabolized in the liver and excreted in the urine. The elimination half-life is long.
It is used orally in the treatment of depression, obsessive-compulsive disorder, bulimia nervosa, and premenstrual dysphoric disorder.

Dosage
Normally at a dose of 20-60 mg / day, depending on the pathology.

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Side effects
Gastrointestinal disorders (dry mouth, nausea, vomiting, dyspepsia, constipation, and diarrhea), neurological effects (anxiety, agitation, nervousness, insomnia, drowsiness, fatigue, headache, tremor, dizziness, convulsions, hallucinations, extrapyramidal effects, sexual dysfunction, and serotonin syndrome), and anorexia and weight loss.
Other effects that have been observed are: excessive sweating, pruritus, rashes and urticaria, angioedema, hypersensitivity and anaphylaxis, hyponatremia, hyperprolactinemia and galactorrhea, glycemia alterations, arthralgia and myalgia, and bleeding disorders.

Contraindications
Nursing mothers

Precautions
Elderly, patients with renal or hepatic insufficiency, epilepsy, heart disease, bleeding disorders, diabetes, or treated with ECT. Treatment should be stopped if a rash appears. Do not drive or operate dangerous machinery during treatment. Withdraw the treatment gradually.

Interactions
The most important is with MAOIs and other drugs that act on the mechanisms of neurotransmission by serotonin, since it can trigger a serotonin syndrome. Increases plasma concentrations of benzodiazepines.
Drugs that inhibit cytochrome P450 or related (such as some macrolides) may increase plasma levels of fluoxetine.
Also, by inhibiting said cytochrome, fluoxetine can increase the levels of some antihistamines such as astemizole and terfenadine, increasing the risk of arrhythmias. Protease inhibitors can also increase fluoxetine levels.
Fluoxetine may increase the action of some anticoagulants.
Fluoxetine can lower the convulsive threshold of antiepileptics, antagonizing its action. There is a risk of CNS toxicity when fluoxetine is administered with sumatriptan-type antimagines and sibutramine.