METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1278-TDS-ENG-2025

METFORMINA HCL (EUR. PH.)		
DESCRIPTION DCI: METFORMIN HYDROCHLORIDE	DESCRIPTION DOE: METFORMINA HIDROCLORURO	
CAS Nº: 1115-70-4	EC Nº: 214-230-6	AEMPS CODE: 1359CH
MOL. WEIGHT: 165,6	MOL. FORMULA: C4H11N5HCl	ARTICLE CODE: 1278

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystals
Solubility	Freely soluble in water, slightly soluble in ethanol (96 %), practically insoluble in acetone and in methylene chloride
Identification B	Complies
Identification E	Complies
Appearance of solution	Clear and colourless
Impurity F	=< 0.05 %
Related substances	
Impurity A	=< 0.02 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a dry, cool and well-ventilated place. Keep away from sources of heat.

REMARKS

Metformine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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 and uses
It is an oral antidiabetic of the group of biguanides, used for the therapy of non-insulin dependent diabetes mellitus (type II) or complicated with ketosis, when the diet has failed or treatment with sulfonylureas. It is of choice in obese patients.
It is also used as an adjunct to insulin therapy in unstable diabetes mellitus or insulin-resistant diabetes.
Since METFORMIN is not associated with weight gain, it is an alternative for obese patients who gain weight with sulfonylureas despite dietary changes.
Its mechanism of action is not entirely clear. It does not stimulate the release of insulin, but requires its presence to exert the anti-glycemic effect. The possible mechanism of action includes a delay in the absorption of glucose by the gastrointestinal tract, in addition to increasing the tissue uptake of it, increased sensitivity to insulin, and inhibition of hepatic gluconeogenesis. It is absorbed slowly and incompletely in the digestive tract. The bioavailability without food is 50-60%. The binding to plasma proteins is insignificant. It is excreted unchanged in the urine. The elimination half-life is 2-6 h.

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METFORMIN does not usually decrease blood glucose levels in non-diabetic individuals.
It can be administered together with sulfonylureas.
In aqueous solution it is stable at pH = 4.6 - 4.9.

Dosage
Oral route, usually at a dose of 850 - 1500 mg / day. Times have been used to use doses of up to 2 - 3 g / day.

Side effects
Lactic acidosis may occur, although it is rare if the appropriate indications and dosage are followed.
Other adverse effects include digestive disorders, with gastric fullness, nausea, vomiting, diarrhea, metallic taste, anorexia and, consequently, weight loss.
In case of nausea, vomiting, abdominal pain, loss of appetite or lethargy, the doctor should be consulted, and if this presupposes that the symptoms are caused by lactic acidosis, the patient should be admitted to a hospital to correct it.

Contraindications
Severe renal, hepatic, respiratory or cardiac insufficiency, myocardial infarction, diabetes complicated by ketoacidosis and diabetic coma, as well as in the elderly and severely weakened individuals due to the increased risk of lactic acidosis, in pregnancy, lactation and alcohol intoxication.

Precautions
The drug must be temporarily removed under conditions that predispose tissue hypoxia, such as serious infections, mainly urinary, major bleeding and advanced anemia. Serum creatinine levels should be monitored every 6 months.
In case of intravenous urography, treatment should be discontinued and restored 2 days after the radiological examination.

Interactions
May decrease the hyperglycaemic action of diazoxide.
Its efficacy can be reduced by estrogens, glucose, loop diuretics and thiazides, phenothiazines, calcium antagonists and rifampicin. Its effect can be enhanced by hormonal anabolics, cimetidine, clofibrate, gemfibrozil, ACE inhibitors, non-steroidal anti-inflammatories, salicylates, sulfonamides, chloramphenicol, probenecid, oral anticoagulants, MAOIs and beta-blockers.
The toxicity of METFORMIN can be increased by alcohol.

Formulation examples

METFORMIN capsules
METFORMIN HCl - **500 mg**
for 1 capsule No. 100.