METAPHARMACEUTICAL

TECHNICAL DATA SHEET

2230-TDS-ENG-2026

FENELZINA SULFATO USP		
DESCRIPTION DCI: PHENELZINE SULFATE	DESCRIPTION DOE: FENELZINA SULFATO	
CAS Nº: 156-51-4	EC Nº: 205-856-0	AEMPS CODE: 1508SU
MOL. WEIGHT: 234,28	MOL. FORMULA: C8H12N2·H2SO4	ARTICLE CODE: 2230

ATTRIBUTES	SHOULD BE
Appearance	White to off-white crystalline powder
Identification A	Complies
Identification B	Complies
Identification C	Complies
Assay	98.0 - 102.0 %
Ordinary impurities	Complies
Limit of hydrazine	=< 0.1 %
Loss on drying	=< 1.0 %
pH	1.4 - 1.9
Melting point	164 - 168 ºC

COMPLIES WITH

USP 2025

STORAGE

Store in a cool, dry and well-ventilated place. Protect from direct sunlight.

REMARKS

PHENELZINE SULFATE 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

Phenelzine is an antidepressant of the group of monoamine oxidase inhibitors (MAOIs), an enzyme responsible for the metabolism of various biogenic amines.
Phenelzine is rapidly absorbed in the gastrointestinal tract and reaches the maximum plasma concentration between 2 and 4 h after ingestion. It is metabolized in the liver and excreted in the urine, mostly in the form of metabolites.
The antidepressant activity seems to depend mainly on the inhibition of type A monoamine oxidase, although the mechanism of antidepressant action of these drugs is not exactly known. Phenelzine is used in the treatment of atypical depression, particularly when there are phobic states or associated anxiety, or in patients who have not responded or other antidepressants. The antidepressant effects may take more than a month to appear.

Dosage

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Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869

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Oral route, at a dose of 45 - 90 mg / day.

Side effects

The most frequent adverse effects associated with phenelzine are orthostatic hypotension and episodes of vertigo. Other common side effects are headache, dry mouth, constipation, gastrointestinal disorders (nausea and vomiting) and edema. Drowsiness, weakness and fatigue have been described frequently, although it can also cause stimulation of the SCN with agitation, nervousness, euphoria, restlessness, insomnia and convulsions. In predisposed people can induce psychotic episodes with manic reactions or delirium.

Muscle sweating and tremor, spasms or hyperreflexia may appear, which in cases of overdose can lead to severe hyperpyrexia or neuromuscular irritability. Other reactions observed include blurred vision, urinary retention or problems in urination, exanthemas, leukopenia, sexual dysfunctions and weight gain with a disproportionate appetite. Cases of jaundice have been observed and, exceptionally, fatal progressive hepatocellular necrosis.

Contraindications

It should not be administered to patients with liver diseases, to patients with cerebrovascular disorders, pheochromocytoma, in patients with blood disorders or cardiovascular disorders, the elderly, and agitated patients.

Precautions

They should be administered with caution in epileptic patients, diabetics, and hyperthyroidism.

It should be closely monitored in patients until an improvement in depression is observed, since suicide is an inherent risk in patients with depression. Do not use in bipolar disorder and in the depressive component of schizophrenia.

MAOIs have prolonged effects, which is why patients should not take any type of food or drug that interacts with them, for at least 14 days after stopping treatment. Patients must carry identification cards showing the details of their MAOI treatment. Patients affected by drowsiness should not drive or operate machinery.

Treatment should be withdrawn gradually to reduce the risk of withdrawal symptoms.

Interactions

The major drawback of MAOIs such as phenelzine is that inhibiting monoamine oxidase causes an accumulation of amine-type neurotransmitters. This means that the hypertensive effects of tyramine, which is present in many everyday foods (cheese, meat, yeast extracts, pickled herrings, smoked foods, pods of beans ...) and that is also metabolized by the monoamine oxidase, they can be dangerously increased. MAOIs inhibit the metabolism of some amine-type drugs (especially that of indirectly acting sympathomimetics), which can lead to a dangerous increase in their hypertensive effects. MAOIs also inhibit other drug-metabolizing enzymes and are, therefore, responsible for numerous interactions with other drugs. It also has an additive effect with serotonergic drugs that can result in serotonin syndrome. The administration of sympathomimetics such as amphetamines, dopamine, ephedrine, levodopa, phenylephrine has triggered severe hypertensive reactions and after the use of anorexics and stimulants with sympathomimetic activity such as fenfluramine, methylphenidate. The inhibition of drug-metabolizing enzymes by MAOIs may increase the effects of barbiturates and possibly other hypnotics, hypoglycaemic agents and possibly antimuscarinics. The metabolism of alcohol can be altered and its effects enhanced. Antihypertensives, including guanethidine, reserpine, and methyldopa should be used with caution: cases of hypertensive and hypotensive reactions have been described; the hypotensive effect of beta-blockers and thiazide diuretics may be increased.

The administration of pethidine and possibly other opioid analgesics to patients taking MAOIs also associated with reactions.

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