

TECHNICAL DATA SHEET

002560-TDS-ENG-2023

MAGNESIO HIDROXIDO PH. EUR.					
DESCRIPTION DCI: MAGNESIUM HYDROXIDE		DESCRIPTION DOE: MAGNESIO HIDROXIDO			
CAS Nº: 1309-42-8	EC Nº: 215-170-3		AEMPS CODE: 22HH		
MOL. WEIGHT: 58.32	MOL. FORMULA: Mg(OH)2		ARTICLE CODE: 002560		

ATTRIBUTES	SHOULD BE			
Appearance	White or almost white, fine, amorphous powder			
Solubility	Practically insoluble in water. It dissolves in dilute acids			
Identification A	Conforme			
Identification B	Conforme			
Appearance of solution	Not more intensely coloured than ref. sol. B3			
Soluble substances	=< 2.0 %			
Substances insoluble in acetic acid	=< 0.1 %			
Chlorides	=< 0.1 %			
Sulfates	=< 1.0 %			
Calcium	=< 1.5 %			
Iron	=< 0.07 %			
Loss on ignition	29.0 - 32.5 %			
Assay	95.0 - 100.5 %			
COMPLIES WITH				

European Pharmacopoeia 10.3

STORAGE

Keep the container tightly closed. Store it in a cool and dry place.

REMARKS

MAGNESIUM HYDROXIDE is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Properties and uses

It is a non-absorbable gastric antacid agent. It acts by neutralizing the hydrochloric acid in the stomach, increasing the gastric pH, which also reduces the formation and activity of pepsin. It does not release carbon dioxide.

Administered orally, it reacts relatively quickly with the hydrochloric acid in the stomach. Subsequently, 30-50% of the magnesium ions are absorbed in the small intestine.

The duration of the action as antacid is short and is determined by the emptying time of the stomach, increasing with food. Many times it is administered in antacid preparations together with aluminum compounds, such as aluminum hydroxide, to counteract the constipation produced by the latter.

It is also used as an osmotic laxative.

Dosage

Oral route, in doses of up to 1 g as an antacid or up to 5 g as a laxative. With a dose of more than 5 g, it has a purgative effect.

Side effects

It can produce irritation of the gastrointestinal mucosa and diarrhea. Exceptionally, with high doses and in cases of impaired renal function, it can produce hypermagnesemia.

Contraindications

Situations of electrolyte imbalance and in acute diseases of the gastrointestinal tract, such as appendicitis.



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Precautions

It should be used with caution in patients with renal insufficiency, due to the risk of hypermagnesemia. A special medical check-up should be carried out in cases of liver failure, the elderly, and debilitated patients.

Interactions

It can reduce the oral absorption of atenolol, captopril, cimetidine, digoxin, iron, ketoconazole, nitrofurantoin, penicillamine, quinolones, ranitidine, and tetracyclines.

It can reduce the effect of sucralfate.

It can increase the renal secretion of salicylates.

Incompatibilities

Absorbs carbon dioxide in the presence of water.

Compounding examples

Milk of magnesia

Magnesium hydroxide - 8 %

Citric acid - 0.1 %

Oral lemon essence - 0.05 %

Purified water c.s.p. - 100 g

Shake it before using.