

**Magnesium Oxide**

E530; Magnesii oxidum; Magnesio, óxido de; Magnésium, oxyde de; Magnesiumoxids; Magnesiumoxid; Magnezu tlenek; Magnesiumum Oksit; Magnio oksidas; Nehéz magnézium; Oxid hořečnatý.

Магния Оксид

MgO = 40.30.

CAS — 1309-48-4.

ATC — A02AA02; A06AD02; A12CC10.

ATC Vet — QA02AA02; QA06AD02; QA12CC10.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn*, *US*, and *Viet*. Some pharmacopoeias include a single monograph that permits both the light and heavy varieties while some have 2 separate monographs for the 2 varieties.

**Ph. Eur. 6.2** (Magnesium Oxide, Heavy; Magnesii Oxidum Ponderosum). A fine, white or almost white powder. 15 g has an apparent volume before settling of not more than 60 mL. Practically insoluble in water; dissolves in dilute acids with at most slight effervescence.

**Ph. Eur. 6.2** (Magnesium Oxide, Light; Magnesii Oxidum Leve). A fine, white or almost white, amorphous powder. 15 g has an apparent volume before settling of at least 100 mL. Practically insoluble in water; dissolves in dilute acids with at most slight effervescence.

**USP 31** (Magnesium Oxide). A very bulky, white powder, or a relatively dense, white powder, or a granulated powder. Practically insoluble in water; insoluble in alcohol; soluble in dilute acids. Store in airtight containers.

**Profile**

Magnesium oxide is an antacid with general properties similar to those of magnesium hydroxide (above). It is given in usual oral doses of about 400 mg. It is often given with aluminium-containing antacids such as aluminium hydroxide, which counteract its laxative effect.

Magnesium oxide has been used for its osmotic laxative properties in bowel preparation; oral doses of 3.5 g are given for this purpose, combined with bisacodyl or sodium picosulfate.

Magnesium oxide is also used as a magnesium supplement in deficiency states in oral doses of up to 800 mg (20 mmol) daily. It is also used as a food additive.

**Preparations**

**USP 31:** Alumina Magnesium Carbonate, and Magnesium Oxide Tablets; Aromatic Cascara Fluidextract; Aspirin, Alumina, and Magnesium Oxide Tablets; Citric Acid, Magnesium Oxide, and Sodium Carbonate Irrigation; Magnesium Oxide Capsules; Magnesium Oxide Tablets.

**Proprietary Preparations** (details are given in Part 3)

**Arg.:** Magnefort; Polvo Roge; SG 33; **Austria:** Magnonorm; Magnotab; **Denm.:** Salifax; **Fr.:** Mag 2 Junior; Magocean; Sargemag; Thalagam; **Ger.:** Biolectra Magnesium 240; Biolectra Magnesium 365; Magium; Magnesium Diasporal; Magnesium Tonik; Magnetrans extra; Magnetrans forte; Magno Sanol; **Hung.:** Magnosolv; **NZ:** Mylanta Effervescent; **S.Afr.:** Solumag; **Swed.:** Salifax; **Thai.:** Magoral; **Turk.:** Magnezi Kalsine; **USA:** Mag-200; Mag-Caps; Mag-Ox; Maox; Uro-Mag.

**Multi-ingredient:** numerous preparations are listed in Part 3.

Used as an adjunct in: **Arg.:** Aspirina; Bufferin†; **Braz.:** Bufferin; **Canad.:** Aspirin with Stomach Guard; Bufferin; Tri-Buffered ASA; **Ital.:** Bufferin†; **Pol.:** Aspinag; Cardiofil; **USA:** Adprin-B; Bufferin; Carma Arthritis Pain Reliever; Extra Strength Bayer Plus.

**Magnesium Trisilicate**

E553(a); Magnesii trisilicas; Magnesio, trisilicato de; Magnésium, trisilicate de; Magnesiumtrisilikaatti; Magnesiumtrisilikat; Magnézi-um-trisilikát; Magnezium Trisilikat; Magnio trisilikatas; Trikřerniči-tan hořečnatý.

Магния Трисиликат

CAS — 14987-04-3 (anhydrous magnesium trisilicate); 39365-87-2 (magnesium trisilicate hydrate).

**Description.** Magnesium trisilicate is a hydrated magnesium silicate. The code E553(a) has been applied to both magnesium silicate and to magnesium trisilicate.

**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *US*, and *Viet*.

**Ph. Eur. 6.2** (Magnesium Trisilicate). It has a variable composition corresponding approximately to the formula Mg<sub>3</sub>Si<sub>3</sub>O<sub>8</sub>·xH<sub>2</sub>O containing not less than 29% of magnesium oxide and not less than the equivalent of 65% of silicon dioxide, both calculated with reference to the ignited substance. A white or almost white powder. Practically insoluble in water and in alcohol.

**USP 31** (Magnesium Trisilicate). A compound of magnesium oxide and silicon dioxide with varying proportions of water. It contains not less than 20% of magnesium oxide and not less than 45% of silicon dioxide. A fine, white, odourless, powder, free from grittiness. Insoluble in water and in alcohol. It is readily decomposed by mineral acids.

**Profile**

Magnesium trisilicate is a hydrated magnesium silicate. It is an antacid with general properties similar to those of magnesium hydroxide (p.1743). It may be given in typical oral doses of up to about 500 mg as required, although higher doses have been given. When given orally it reacts more slowly with hydrochloric acid in the stomach than magnesium hydroxide. Magnesium trisilicate is often given with aluminium-containing antacids such as aluminium hydroxide, which counteract its laxative effect.

Magnesium trisilicate is also used as a food additive and as a pharmaceutical excipient.

**Effects on the kidneys.** The formation of renal calculi containing silica is unusual, but has been reported in a small number of patients. In most of these cases, stone formation was attributed to the prolonged, and sometimes excessive, intake of antacids that contained magnesium trisilicate.<sup>1,2</sup>

- Haddad FS, Kouyoumdjian A. Silica stones in humans. *Urol Int* 1986; **41**: 70–6.
- Lee M-H, et al. Silica stone—development due to long time oral trisilicate intake. *Scand J Urol Nephrol* 1993; **27**: 267–9.

**Preparations**

**BP 2008:** Compound Magnesium Trisilicate Oral Powder; Compound Magnesium Trisilicate Tablets; Magnesium Trisilicate Mixture;

**USP 31:** Alumina and Magnesium Trisilicate Oral Suspension; Alumina and Magnesium Trisilicate Tablets; Magnesium Trisilicate Tablets.

**Proprietary Preparations** (details are given in Part 3)

**Multi-ingredient:** numerous preparations are listed in Part 3.

Used as an adjunct in: **Swed.:** Deltison.

**Manna**

Maná; Manne en Larmes.

Манна

**Profile**

Manna is the dried exudation from the bark of the European flowering ash, *Fraxinus ornus* (Oleaceae), containing about 40 to 60% of mannitol (p.1330). It has been used as an osmotic laxative.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Multi-ingredient:** **Cz.:** Dr Theiss Rheuma Creme†; Dr Theiss Schweden Krauter; Naturland Grosser Swedenbitter†; **Ger.:** florabio Mann-Feigen-Sirup mit Senna†; florabio Manna-Feigen; Infi-tract†.

**Mebeverine Hydrochloride** (BANM, USAN, rINNM)

CSAG-144; Hidrochloruro de mebeverina; Mébévérine, chlorhydrate de; Mebeverini hydrochloridum. 4-[Ethyl(4-methoxy- $\alpha$ -methylphenethyl)amino]butyl veratrate hydrochloride.

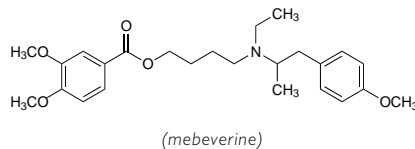
Мебеверина Гидрохлорид

C<sub>25</sub>H<sub>35</sub>NO<sub>5</sub>·HCl = 466.0.

CAS — 3625-06-7 (mebeverine); 2753-45-9 (mebeverine hydrochloride).

ATC — A03AA04.

ATC Vet — QA03AA04.

**Pharmacopoeias.** In *Br*.

**BP 2008** (Mebeverine Hydrochloride). A white or almost white crystalline powder. Very soluble in water; freely soluble in alcohol; practically insoluble in ether. A 2% solution in water has a pH of 4.5 to 6.5. Store in airtight containers at a temperature not exceeding 30°. Protect from light.

**Adverse Effects and Precautions**

Although adverse effects appear rare, gastrointestinal disturbances, dizziness, headache, insomnia, anorexia, and decreased heart rate have been reported in patients receiving mebeverine. Cases of hypersensitivity, including erythematous rash, urticaria, and angioedema, have also been reported. Mebeverine should be avoided in patients with paralytic ileus. Based on theoretical concerns, it should be used with care in patients with marked hepatic or renal impairment, and those with cardiac disorders such as heart block.

**Cystic fibrosis.** A 24-year-old man with cystic fibrosis, given mebeverine hydrochloride for lower abdominal pain and constipation, was found to have a perforated stercoral ulcer with generalised peritonitis.<sup>1</sup> It was suggested that mebeverine produced colonic stasis, which predisposed the patient to ulceration,<sup>1</sup> but

the manufacturers<sup>2</sup> considered that the development of constipation and distal intestinal syndrome (meconium ileus equivalent) in this patient precipitated the development of stercoral ulceration. It was recommended<sup>1</sup> that antispasmodics such as mebeverine should not be used for the symptomatic treatment of distal intestinal syndrome in cystic fibrosis.

- Hassan W, Keaney N. Mebeverine-induced perforated colon in distal intestinal syndrome of cystic fibrosis. *Lancet* 1990; **335**: 1225.
- Whitehead AM. Perforation of colon in distal intestinal syndrome of cystic fibrosis. *Lancet* 1990; **336**: 446.

**Porphyria.** Mebeverine hydrochloride is considered to be unsafe in patients with porphyria because it has been shown to be porphyrinogenic in *in-vitro* systems.

**Pharmacokinetics**

Mebeverine is rapidly absorbed after oral doses with peak plasma concentrations occurring in 1 to 3 hours. It is 75% bound to albumin in plasma. Mebeverine is completely metabolised by hydrolysis to veratric acid and mebeverine alcohol, the latter of which may then be conjugated. The metabolites are excreted in the urine.

**Uses and Administration**

Mebeverine hydrochloride is an antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract. It is used in conditions such as irritable bowel syndrome (p.1699) in a usual oral dose of 135 mg three times daily before meals; 100 mg three times daily has also been used. A modified-release preparation is also available, taken as 200 mg twice daily. The embonate is also used for oral liquid preparations in a dose equivalent to 150 mg of the hydrochloride three times daily. The *BNFC* suggests that the following hydrochloride-equivalent doses may be given three times daily, based on age:

- 25 mg for those aged 3 to 4 years
- 50 mg for those 4 to 8 years
- 100 mg for those 8 to 10 years
- 135 to 150 mg for those over 10 years

**Preparations**

**BP 2008:** Mebeverine Tablets.

**Proprietary Preparations** (details are given in Part 3)

**Arg.:** Duspatalin; **Austral.:** Coles; Colofac; **Austria:** Colofac; **Belg.:** Duspatalin; Spasmonal†; **Braz.:** Duspatalin; **Chile:** Doloverina; Duspatal; Evadol; Meditoina; **Cz.:** Duspatalin; **Denm.:** Duspatalin; **Fr.:** Colopriv; Duspatalin; Spasmopriv; **Ger.:** Duspatal; Mebemerck; **Gr.:** Duspatalin; Gastromin†; **Hong Kong:** Duspatalin; **Hung.:** Duspatalin; **India:** Colospa; **Indon.:** Duspatalin; Irbosy; **Irl.:** Colofac; **Israel:** Cololat; **Ital.:** Duspatal; **Malaysia:** Duspatalin; Lezpain; Mebetin; **Mex.:** Arlyu; **Neth.:** Duspatal; **NZ:** Colofac; **Philipp.:** Duspatalin; **Pol.:** Duspatalin; **Port.:** Duspatal; **Rus.:** Duspatalin (Дюспаталин); **S.Afr.:** Bevispas; Colofac; **Singapore:** Duspatalin; Mebetin; **Spain:** Duspatalin; **Switz.:** Duspatalin; **Thai.:** Colofac; Duspatalin; Menosor; **Turk.:** Duspatalin; Duspaverin; **UK:** Colofac; Equilon†; IBS Relief†.

**Multi-ingredient:** **Hong Kong:** Fyogel Mebeverine†; **Irl.:** Fyogel Mebeverine; **UK:** Fyogel Mebeverine.

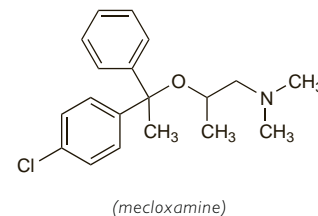
**Mecloxamine Citrate** (rINNM)

Citrato de mecloxamina; Mécloxamine, Citrate de; Mecloxamini Citras. 2-[1-(4-Chlorophenyl)-1-phenylethoxy]-N,N-dimethyl-1-propanamine citrate.

Меклоксamina Цитрат

C<sub>19</sub>H<sub>24</sub>ClNO, C<sub>6</sub>H<sub>8</sub>O<sub>7</sub> = 510.0.

CAS — 5668-06-4 (mecloxamine); 56050-03-4 (mecloxamine citrate).

**Profile**

Mecloxamine citrate is reported to have antimuscarinic properties and has been used for its antiemetic action in antimigraine preparations.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Multi-ingredient:** **Austria:** Avamigran; **Turk.:** Avmigran.