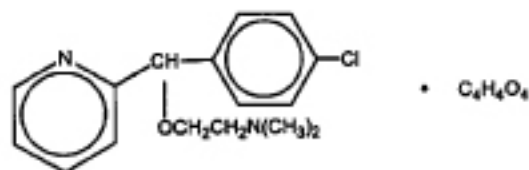
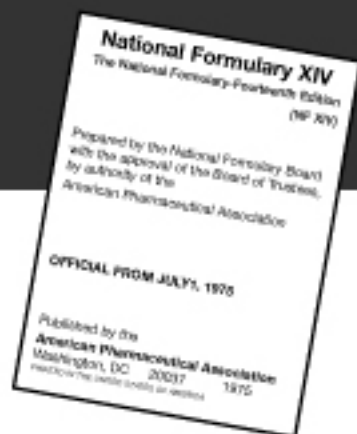


MONOGRAPH

Carbinoxamine Maleate



C₁₆H₁₉ClN₂O₄ 406.87

Ethanamine, 2-[(4-chlorophenyl)-2-pyridinylmethoxy]-N, N-dimethyl-, (Z)-2-butenedioate (1:1)

2-[p-Chloro- x-[2-(dimethylamino) ethoxy]benzyl]pyridine maleate (1:1) [3505-38-2]

Category—Antihistaminic.

Usual Dose—4 mg three or four times daily.

Usual Dose Range—4 to 8 mg.

Description—Carbinoxamine Maleate occurs as a white, odorless, crystalline powder.

Solubility—Carbinoxamine Maleate is very soluble in water, is freely soluble in alcohol and in chloroform, and is very slightly soluble in ether.

Carbinoxamine Maleate, dried at 105° for 2 hours, contains not less than 98.0 percent and not more than 102.0 percent of C₁₆H₁₉ClN₂O₄.

Packaging and storage—Preserve Carbinoxamine Maleate in tight, light-resistant containers.

Reference standards—

NF Carbinoxamine Maleate Reference Standard—Dry at 105° for 2 hours before using.

Melting range, Class Ia—Carbinoxamine Maleate, previously dried, melts between 116 and 121°. Infrared absorption, page 963—The infrared absorption spectrum of a mineral oil dispersion of Carbinoxamine Maleate, previously dried, exhibits maxima only at the same wavelengths as that of *NF Carbinoxamine Maleate Reference Standard*, similarly measured.

Ultraviolet absorption—The ultraviolet absorption spectrum of a 1 in 20,000 solution of Carbinoxamine Maleate in methanol exhibits maxima and minima at the same wavelengths as that of *NF Carbinoxamine Maleate Reference Standard*, similarly measured, and the respective absorptivities, calculated on the dried basis, at the point of maximum absorbance occurring at about 260 nm, do not differ by more than 3.0%.

pH—The pH of a solution of Carbinoxamine Maleate (1 in 100) is between 4.6 and 5.1.

Loss on drying—Dry Carbinoxamine Maleate at 105° for 2 hours: it loses not more than 0.5% of its weight.

Residue on ignition—The limit is 0.1%.

Assay—Dissolve about 400 mg of Carbinoxamine Maleate, previously dried and accurately weighed, in 50 ml of glacial acetic acid, add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid to a blue-green end-point. Perform a blank determination, and make any necessary correction. Each ml of 0.1 N perchloric acid is equivalent to 20.34 mg of C₁₆H₁₉ClN₂O₄.