

Dexbrompheniramine maleate is normally given as an ingredient of decongestant preparations containing pseudoephedrine. The dose of dexbrompheniramine maleate by mouth in these combinations is 2 mg up to four times daily. Children over 6 years can be given 1 mg up to four times daily.

Modified-release oral preparations of brompheniramine maleate or dexbrompheniramine maleate are available in some countries; dosage is specific to a particular formulation.

Preparations

BP 2008: Brompheniramine Tablets;
USP 31: Brompheniramine Maleate Elixir; Brompheniramine Maleate Injection; Brompheniramine Maleate Tablets; Dexbrompheniramine Maleate and Pseudoephedrine Sulfate Oral Solution.

Proprietary Preparations (details are given in Part 3)

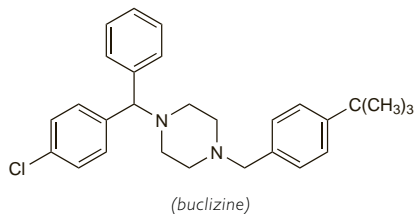
Fr.: Dimegan; **Malaysia:** Bomex; **Singapore:** Bomexf; **Thai:** Babycold; **Bomine;** Dimetane; **UK:** Dimotanef; **USA:** Bidhist; Dimetane; J-Tan; Lodrane 12; Lodrane 24; Oraminic II; P-Tex.

Multi-ingredient: **Arg.:** Factus; **Austral.:** Dimetapp; Dimetapp DM; **Braz.:** Bialerge; Deconex Plus; Deconex Plus Expectorate; Dimetapp; Winter AP; **Canada:** Dimetane Expectant C; Dimetane Expectant DC; Dimetapp Cold; Dimetapp DM Cough & Cold; Dimetapp Oral Infant Cold & Fever Drops; Dimetapp Oral Infant Drops; Dimetapp-C; Drixoral; Drixoral Day/Night; **Chile:** Disofrin; **Cz.:** Disophrol; **Fin.:** Disofrolf; **Fr.:** Dimetane Expectantant Enfant; Martigene; **Gr.:** Dimetapp New; **Hong Kong:** Brom-PP; Brom-Ramine Compound; Bromhexine Compound; Bromphenex; DF Multi-Symptom; Dimaxin; Dimeta-2; Dimetapp; Drixoral; Eascol; ENT; Eurotapp; Uhinist; Vidatapp; Vidatapp Forte; **Hung.:** Disophrolf; **Indon.:** Alco Plus; Alco Plus DMP; Drixoral; **Ir.:** Dimetane Co; **Malaysia:** Drixoral; Rinafort; **Mex.:** Afrinex; Cripofen; Dimetapp; **NZ:** Dimetapp; Dimetapp DM Cold & Cough; **Philipp.:** Dimerrin; Dimetapp; Hisdec; Nasatapp; Noster; Penbroso; PPB; Rhinodex; Rhinotapp; Snizee; Zeditapp; **Pol.:** Disophrol; **Port.:** Constipal; Ilvico N; **S.Afr.:** Dimetapp; Ilvico; **Singapore:** Dimetapp; Drixoral; Rinafort; **Spain:** Disofrol; Ilvico; **Swed.:** Disofrol; **Switz.:** Disofrol; Rupton; **Thai:** Asiatapp; Bepeho; Bepeho-G; Bluco; Bromavon; Bromesep Elixir; Bromesep Expectantant; Bromped; Bromtussia; Bromtussia DC; Brontus; Centapp; Daminat; Dimetapp; Meditapp; Meditapp Expectantant; MEXY; Minraf; Nartap; Nasorest; Pharfed; Polamine; Polydine; Polydrop; Postap; Postap Expectantant; Rhinadine; Rhinophen-C; Uhinist; **Turk.:** Disophrol; **UK:** Dimotane Co; Dimotane Expectantant; Dimotane Plus; **USA:** 12 Hour Antihistamine Nasal Decongestant; 12 Hour Cold; Accuhist; Accuhist DM Pediatric; Accuhist PDX; Alcolol DM; Allent; Anaplex DM; Anaplex HD; Andehist DM; Andehist; Brofed; Bromadine-DM; Bromarest DX; Bromatan-DM; Bromatane DX; Bromfed; Bromfed-DM; Bromfed-PD; Bromfenex; Bromhist; Bromhist PDX; Bromhist-DM; Bromhist-NR; Bromphen DX Cough; Brompheniramine Cough; Brovex PD; C-Tan D; Carboxex DM; Coldec DM; Comtrex Acute Head Cold; CPB WC; Cytuss-HC NR; Dallergy DM; DEKA; Dexaphen-SA; Dimetane Decongestant; Dimetapp; Dimetapp Cold & Fever; Dimetapp DM; Dimetapp Nighttime Flu; Disobrom; Disophrol; Dristan Allergy; Dristan Cold Maximum Strength Multi-symptom Formula; Drixomed; Drixoral; Drixoral Cold & Allergy; Drixoral Cold & Flu; Drixoral Plus; Drocon-CS; Endafed; Histacol DM; Histussin HC; Iofed; Lodrane; Lodrane 12D; Lodrane D; Lortuss DM; M-END WC; Maximum Strength Dristan Cold; Myphatane DX; Nalex AC; Neo DM; P-Hist DM; PBM Allergy; Pediahist DM; Q-Tapp DM; Respahist; Resperal-DM; Rondamine-DM; Rondex; Seradex-LA; Sildec-DM; Sinadrin Plus; Touro A & H; Touro Allergy; Tusdec-DM; Tusnel-HE; Tussall; ULTRAAbrom; VaZol-D; Vazotab; Vazotan; Vazotuss HC; Zotex-PC; **Venez.:** Dimetapp; Ilvico; Metofedrin.

Bucizine Hydrochloride (BANM, USAN, rNINM)

Bucizine, Chlorhydrate de; Bucizini Hydrochloridum; Buklizin Hidroklorür; Hidrocloruro de buclizina; NSC-25141; UCB-4445. (RS)-1-(4-tert-Butylbenzyl)-4-(4-chlorobenzhydryl)piperazine dihydrochloride.

Букизина Гидрохлорид
 $C_{28}H_{33}ClN_2 \cdot 2HCl = 505.9$.
CAS — 82-95-1 (bucizine); 129-74-8 (bucizine hydrochloride).
ATC — R06AE01.
ATC Vet — QR06AE01.



Pharmacopoeias. In Br:

BP 2008 (Bucizine Hydrochloride). A white or slightly yellowish, crystalline powder. Practically insoluble in water; very slightly soluble in alcohol; sparingly soluble in chloroform and in propylene glycol.

Adverse Effects and Precautions

As for the sedating antihistamines in general, p.561.

Interactions

As for the sedating antihistamines in general, p.563.

Uses and Administration

Bucizine hydrochloride, a piperazine derivative, is a sedating antihistamine with antimuscarinic and moderate sedative ac-

tions. It is used mainly for its antiemetic action, particularly in the prevention of motion sickness (p.564) and with analgesics in the treatment of migraine (p.616). In some countries it is given in the management of allergic conditions and in pruritic skin disorders (p.565). Bucizine has also been used in the treatment of vertigo (p.565) associated with disorders of the vestibular system, although its value in these conditions remains to be established.

To prevent motion sickness, buclizine hydrochloride is given at least 30 minutes before travelling in an oral dose of 25 or 50 mg, which may be repeated, if necessary, after 4 to 6 hours. The usual dose to alleviate nausea is 25 or 50 mg daily up to 100 mg daily in divided doses; in severe cases up to 150 mg daily has been given.

In the treatment of migraine, buclizine hydrochloride is given in usual doses of 12.5 mg at the start of an attack or when one is known to be imminent; children aged 10 to 14 years may be given 6.25 mg and older children the usual adult dose.

In pruritic skin disorders the usual dose of buclizine hydrochloride is 25 to 50 mg daily.

Preparations

Proprietary Preparations (details are given in Part 3)

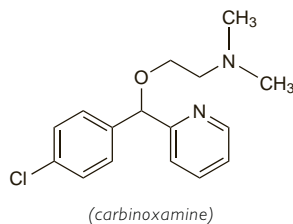
Belg.: Longifene; **Braz.:** Bucina; Postafen; **Fr.:** Aphilan; **Hong Kong:** Longifene; **India:** Longifene; **Malaysia:** Buchzine; Longifene; Longimin; **Port.:** Bucina; Postafeno; **S.Afr.:** Longifene; **Singapore:** Longifene; Panzimine; **Turk.:** Longifene; **USA:** Buciladin-S Softab.

Multi-ingredient: **Braz.:** Apetibe; Apetil; Bucilamin; Bucifen-Vit; Bucimax; Buciplex; Carnabol; Complexit; Klizin; Nutri-Ped; Nutrimaiz SM; Pepsivit; Pondusvitam; Profol; Propan; Vitaler; **Ger.:** Migralave N; **Ir.:** Migraleve; **Israel:** Migraleve; **Philipp.:** Appebon; Appebon with Iron; Appeton; Biotermin AS; Ferlette; Medifortan-AS; Pedifortan-AS; Propan; Propan with Iron; Regeon-E Plus; **Port.:** Migraleve; **S.Afr.:** Vomifene; **Spain:** Migraleve; **Switz.:** Migraleve; **UK:** Migraleve; **Venez.:** Dexapostafen.

Carbinoxamine Maleate (BANM, rNINM)

Carbinoxamine, Maleate de; Carbinoxamini Maleas; Karbinok-samin Maleat; Maleato de carbinoxamina. 2-[4-Chloro- α -(2-pyridyl)benzyloxy]-NN-dimethylethylamine hydrogen maleate.

Карбиноксамина Малат
 $C_{16}H_{19}ClN_2O \cdot C_4H_4O_4 = 406.9$.
CAS — 486-168 (carbinoxamine); 3505-38-2 (carbinoxamine maleate).
ATC — R06AA08.
ATC Vet — QR06AA08.



Pharmacopoeias. In US:

USP 31 (Carbinoxamine Maleate). A white, odourless, crystalline powder. Soluble 1 in less than 1 of water, 1 in 1.5 of alcohol and of chloroform, and 1 in 8300 of ether. pH of a 1% solution in water is between 4.6 and 5.1. Store in airtight containers. Protect from light.

Adverse Effects and Precautions

As for the sedating antihistamines in general, p.561.

Interactions

As for the sedating antihistamines in general, p.563.

Uses and Administration

Carbinoxamine maleate, a monoethanolamine derivative, is a sedating antihistamine with antimuscarinic, significant sedative, and serotonin antagonist effects. Carbinoxamine maleate is used for the relief of allergic conditions such as rhinitis (p.565), and is a common ingredient of compound preparations for symptomatic treatment of coughs and the common cold (p.564).

Dose recommendations for carbinoxamine maleate may vary between preparations. Licensed US product information suggests a usual oral dose of carbinoxamine maleate in adults of 4 to 8 mg given 3 or 4 times daily. Children of 2 to 3 years of age may be given a dose of 2 mg three or four times daily, children aged 3 to 6 years given 2 to 4 mg three or four times daily, and those above 6 years given 4 to 6 mg three or four times daily. Lower doses, sometimes less than half these licensed in the US, may be used in other countries. Carbinoxamine polistirex has also been given by mouth.

Preparations

USP 31: Carbinoxamine Maleate Tablets; Pseudoephedrine Hydrochloride, Carbinoxamine Maleate, and Dextromethorphan Hydrobromide Oral Solution.

Proprietary Preparations (details are given in Part 3)

Arg.: Omega 100; **Mon.:** Allergofon; **Thai:** Histin; Sinumine; **USA:** Carboxine; Histex CT; Histex I/E; Histex PD; Palgic; Pediatex.

Multi-ingredient: **Arg.:** Aseptobron C; Cobenzil Compuesto; Omega 100 Expectantant; Rondex Compositum; Rondex; Torfan H; **Austria:**

Rhinopront; **Belg.:** Rhinopront; **Braz.:** Afebrin; Geprij; Iodeto de Potassio Composto; Naldecon; Naldecon Pediatric; Nasaliv; Neolefin; Neolefin Baby; Resprin; **Chile:** Matinor; Rhinopront; Rinoform; **Cz.:** Rhinopront; Rhinotussal; **Ger.:** Rhinopront; Rhinotussal; **Gr.:** Rhinopront-S; Rhinopront; Rondex; **Hong Kong:** Became; Cortussal; Metopex; Rhinopront; **Hung.:** Rhinopront; **India:** Clistin; **Indon.:** Kenantist; **Israel:** Rhinovist; **Malaysia:** Became; Rhinopront; **Mex.:** Lentostamin; Prindex; **Singapore:** Became; Rhinopront; **Spain:** Rinomax; Rinoretard; **Switz.:** Rhinopront; Rhinotussal; **Thai:** Rhinar; Rhinohist; Rhinopront; Rondex-DM; **Turk.:** Rhinopront; Rhinotussal; **UAE:** Fluzal; **USA:** Andehist DM; Andehist; Aridex; Carbinoxamine Compound; Carbiset; Carboxex; Carbodex DM; Carboxex DM; Carboxine-PSE; Coldec D; Cordron-D; Cordron-DM; Cydex DM; Cydex; Dacec-A; Decahist-DM; DM'ax; Histex HC; Nacon; Norel LA; Palgic DS; Palgic-D; Pediatex-D; Pediatex-DM; Pseudo-Car DM; Rondex; Sildec-DM; Trituss-A; Xiral-Hist DM; **Venez.:** Au-rimel; Resprin; Rhinopront; Rondex; Sondinal.

Cetirizine Hydrochloride

(BANM, USAN, rNINM)

Cetirizin-dihydrochlorid; Cetirizin-dihydrochlorid; Cetirizindihydrochlorid; Cétirizine, Chlorhydrate de; Cétirizine, dichlorhydrate de; Cetirizini dihydrochloridum; Cetirizini Hydrochloridum; Cetirizino dihydrochloridas; Cetryryzyny dichlorowodorek; Hydrocloruro de cetirizina; P-071; Setirtisindihydrochlorid; Setirizin Hidroklorür; UCB-P071. The dihydrochloride of 2-[4-(4-chlorobenzhydryl)piperazin-1-yl]ethoxyacetic acid.

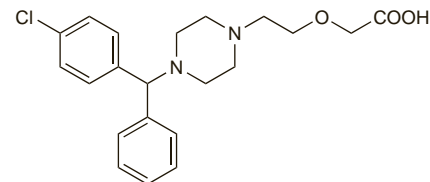
Цетиризина Гидрохлорид

$C_{21}H_{25}ClN_2O_3 \cdot 2HCl = 461.8$.

CAS — 83881-51-0 (cetirizine hydrochloride); 83881-52-1 (cetirizine hydrochloride).

ATC — R06AE07.

ATC Vet — QR06AE07.



Pharmacopoeias. In Eur. (see p.vii).

Ph. Eur. 6.2 (Cetirizine Dihydrochloride; Cetirizine Hydrochloride BP 2008). A white or almost white powder. Freely soluble in water; practically insoluble in acetone and in dichloromethane. A 5% solution in water has a pH of 1.2 to 1.8. Protect from light.

Adverse Effects and Precautions

As for the non-sedating antihistamines in general, p.561. Reduced dosage is recommended for patients with hepatic or renal impairment (see under Uses and Administration, below).

Arrhythmias. The ECG effects of cetirizine were studied¹ in normal subjects; doses of up to six times the usual recommended dose did not prolong the QT interval. Additionally, the FDA² in the USA and representatives of the manufacturers³ in Belgium did not find any association between cetirizine and the development of ventricular arrhythmias. However, there has been a subsequent report⁴ of torsade de pointes after overdosage with cetirizine in a hypokalaemic patient undergoing haemodialysis for chronic renal failure. See also p.562.

1. Sale ME, et al. The electrocardiographic effects of cetirizine in normal subjects. *Clin Pharmacol Ther* 1994; **56**: 295-301.
2. Himmel MH, et al. Dangers of non-sedating antihistamines. *Lancet* 1997; **350**: 69.
3. Coulie P, et al. Non-sedating antihistamines and cardiac arrhythmias. *Lancet* 1998; **351**: 451.
4. Renard S, et al. Torsades de pointes induites par surdosage en cetirizine. *Arch Mal Coeur Vaiss* 2005; **98**: 157-61.

Effects on the liver. Life-threatening hepatitis developed in a 23-year-old man who had been taking cetirizine long-term for atopic dermatitis.¹ He recovered after treatment with prednisolone.

There has been a report of recurrent acute hepatitis associated with the short-term use of cetirizine for seasonal allergic rhinitis in a 26-year-old man.²

1. Watanabe M, et al. Severe hepatitis in a patient taking cetirizine. *Ann Intern Med* 2001; **135**: 142-3.
2. Pompili M, et al. Recurrent acute hepatitis associated with use of cetirizine. *Ann Pharmacother* 2004; **38**: 1844-7.