USP 31 (Dicyclomine Hydrochloride). A fine white, practically odourless, crystalline powder. Soluble 1 in 13 of water, 1 in 5 of alcohol, 1 in 2 of chloroform and of glacial acetic acid, and 1 in 770 of ether. pH of a 1% solution in water is between 5.0 and 5.5.

Adverse Effects, Treatment, and Precautions

As for Atropine Sulfate, p.1219. Dicycloverine hydrochloride should not be given to infants younger than 6 months of age.

Apnoea. Reports[1-3] of severe apnoea in infants aged 5 to 10 weeks associated with the use of dicycloverine.

1. Williams J, Watkin-Jones R. Dicyclomine: worrying symptoms associated with its use in some small babies. *BMJ* 1984; **288:** 901.
2. Edwards PDL. Dicyclomine in babies. *BMJ* 1984; **288:** 1230.
3. Spoudeas H, Shribman S. Dicyclomine in babies. *BMJ* 1984; **288:** 1230.

Pregnancy. For a review of the risks to the fetus of antiemetic therapy during pregnancy, with particular reference to *Debendox* (*Bendectin*: dicycloverine with doxylamine and pyridoxine), see under Antihistamines on p.563.

Interactions

As for antimuscarinics in general (see Atropine Sulfate, p.1220).

Uses and Administration

Dicycloverine hydrochloride is a tertiary amine antimuscarinic with effects similar to but weaker than those of atropine (p.1219); it also has a direct antispasmodic action.

Dicycloverine is used in gastrointestinal spasm, particularly that associated with the irritable bowel syndrome. For adults, 10 to 20 mg of dicycloverine hydrochloride is given orally 3 times daily; in the USA, up to 40 mg four times daily has been recommended where adverse effects permit. Children aged 6 months to 2 years may be given 5 to 10 mg up to 3 or 4 times daily; doses are usually given 15 minutes before meals. Children aged 2 to 12 years may be given 10 mg three times daily.

Dicycloverine hydrochloride may be given intramuscularly in doses of 20 mg given 4 times daily to patients in whom oral therapy is temporarily impractical, but should not be used for longer than 1 to 2 days.

Preparations

BP 2008: Dicycloverine Oral Solution; Dicycloverine Tablets;
USP 31: Dicyclomine Hydrochloride Capsules; Dicyclomine Hydrochloride Injection; Dicyclomine Hydrochloride Syrup; Dicyclomine Hydrochloride Tablets.

Proprietary Preparations (details are given in Part 3)

Arg.: Babypasmil; ***Austral.:*** Merbentyl†; ***Braz.:*** Bentyl; ***Canad.:*** Bentylol; Formulex†; Lomine; ***Hong Kong:*** Dicymine; ***India:*** Cyclominol; Cyclopam; Dysmen; Spasmo-Proxyvon; Spasmonil; ***Irl.:*** Merbentyl†; ***Israel:*** Notensyl; ***Mex.:*** Bentyl; Clominal; Dicigon; Diclomin; Sediclon; ***NZ:*** Merbentyl†; ***Philipp.:*** Bentyl; Dilomin; Relestal; Spasdon; ***Port.:*** Optimal†; ***Rus.:*** Trigan (Триган); ***S.Afr.:*** Clomin†; Medicyclomine†; Merbentyl; ***Thai.:*** Dicomin; Dicymine; ***UK:*** Merbentyl; ***USA:*** Antispas; Bentyl; Byclomine; Dibent; Or-Tyl; ***Venez.:*** Ciclan†; Diciclor†; Mabex.

Multi-ingredient: ***Arg.:*** Dafne; ***Chile:*** Profisin; ***Hong Kong:*** Colimix; Dicymine Co; Epilon; Veragel; ***India:*** Colimex; Colirid; Cyclo-Meff; Cyclopam; Diclospa; Dysmen; Nicispas; Normaxin; Parvon-Spas; Spasmo-Proxyvon; Spasmo-Proxyvon Forte; Spasmocip Plus; Spasmoflexon†; Spasmonil; Spasmonil Plus; Trigan-D; Ze-Spas; ***Ital.:*** Merankol Pastiglie; ***Malaysia:*** Colimix; Uphaco†; ***Mex.:*** Alphalox-D; Exhidrol; Farcolan; ***Port.:*** Nausefe; ***Rus.:*** Trigan-D (Триган-Д); ***S.Afr.:*** Acugel; Alkalite D; Alumag D; Alumite D; Asic; Betaclomin; Co-Gel; Gelumen; Kolantyl; Medigel; Microgel; Neutragel-D; pH 550†; Propan Gel-S; Remotrox; Spasmogel; ***Singapore:*** Colimix; Meclosil; Veragel DMS; ***Spain:*** Colchimax; Neocolan; ***Thai.:*** Berclomine; Biodan†; Cymine; Difemic; Kremil-S; Mainnox; Med-Anspasmic†; Spasticone; Veragel; ***UK:*** Kolanticon; ***Venez.:*** Clopina†; Dicigel.

Difemerine Hydrochloride *(rINNM)*

Difémérine, Chlorhydrate de; Difemerini Hydrochloridum; Hidrocloruro de difemerina; UP-57. 2-Dimethylamino-1,1-dimethylethyl benzilate hydrochloride.

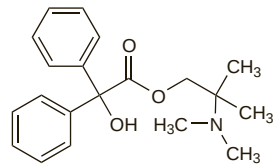
Дифемерина Гидрохлорид

$C_{20}H_{25}NO_3$,HCl = 363.9.

CAS — 80387-96-8 (difemerine); 70280-88-5 (difemerine hydrochloride).

ATC — A03AA09.

ATC Vet — QA03AA09.



(difemerine)

Profile

Difemerine hydrochloride is an antimuscarinic with effects similar to those of atropine (p.1219) and was used in the symptomatic treatment of visceral spasms.

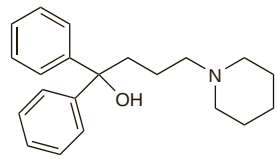
Difenidol Hydrochloride *(BANM, rINNM)*

Difénidol, Chlorhydrate de; Difenidoli Hydrochloridum; Diphenidol Hydrochloride *(USAN)*; Hidrocloruro de difenidol; SKF-478 (difenidol); SKF-478-A; SKF-478-J (difenidol embonate). 1,1-Diphenyl-4-piperidinobutan-1-ol hydrochloride.

Дифенидола Гидрохлорид

$C_{21}H_{27}NO$,HCl = 345.9.

CAS — 972-02-1 (difenidol); 3254-89-5 (difenidol hydrochloride); 26363-46-2 (difenidol embonate).



(difenidol)

Pharmacopoeias. In *Chin.* and *Jpn.*

Profile

Difenidol hydrochloride is an antiemetic that probably acts through the chemoreceptor trigger zone. It is claimed to control vertigo by means of a specific effect on the vestibular apparatus. Difenidol also has a weak peripheral antimuscarinic action.

It has been used in the treatment of some forms of nausea and vomiting (p.1700) such as those associated with surgery, radiotherapy, and cancer chemotherapy. It has also been used for the symptomatic treatment of vertigo (p.565), nausea and vomiting due to Ménière's disease (p.564), and other labyrinthine disturbances.

It has been given in oral doses equivalent to 25 to 50 mg of difenidol every 4 hours as required. Difenidol hydrochloride has also been given parenterally.

Preparations

Proprietary Preparations (details are given in Part 3)

Braz.: Vontrol†; ***Chile:*** Vontrol; ***Hong Kong:*** Cephadol; ***Jpn:*** Cephadol; ***Malaysia:*** Cephadol; ***Mex.:*** Biomitin; Diphafen; Hemetiken; Lansenol; Nautrol; Normavom; Serratol; Sons; Vontrol; Voxamine; ***Philipp.:*** Cephadol; ***Singapore:*** Cephadol†; ***Thai.:*** Cephadol.

Difenoxin *(BAN, USAN, rINN)*

Difenoxilic Acid; Difenoxina; Difénoxine; Difenoxinum; Diphenoxylic Acid; McN-JR-15403-11. 1-(3-Cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid.

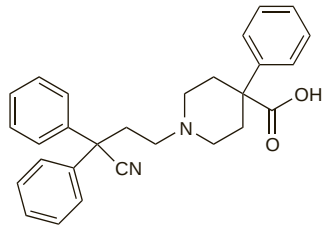
Дифеноксин

$C_{28}H_{28}N_2O_2$ = 424.5.

CAS — 28782-42-5.

ATC — A07DA04.

ATC Vet — QA07DA04.



Difenoxin Hydrochloride *(BANM, rINNM)*

Difénoxine, Chlorhydrate de; Difenoxini Hydrochloridum; Difenoxylic Acid Hydrochloride; Diphenoxylic Acid Hydrochloride; Hidrocloruro de difenoxina; R-15403.

Дифеноксина Гидрохлорид

$C_{28}H_{28}N_2O_2$,HCl = 461.0.

CAS — 35607-36-4.

ATC — A07DA04.

ATC Vet — QA07DA04.

Profile

Difenoxin is the principal active metabolite of diphenoxylate (p.1724) and has similar actions and uses. It is given orally as the hydrochloride, but doses are in terms of the base; difenoxin hydrochloride 1.1 mg is equivalent to about 1 mg of difenoxin.

In the treatment of diarrhoea (p.1694), the usual dose in adults is the equivalent of difenoxin 2 mg initially, followed by 1 mg after each loose stool or every 3 to 4 hours as required, up to a maximum of 8 mg daily.

Preparations of difenoxin usually contain subclinical amounts of atropine sulfate in an attempt to discourage abuse.

Preparations

Proprietary Preparations (details are given in Part 3)

USA: Motofen.

Dihexyverine Hydrochloride *(USAN, rINNM)*

Dihexiverine Hydrochloride; Dihexyvérine, Chlorhydrate de; Dihexyverini Hydrochloridum; Hidrocloruro de dihexiverina; JL-1078. 2-Piperidinoethyl bicyclohexyl-1-carboxylate hydrochloride.

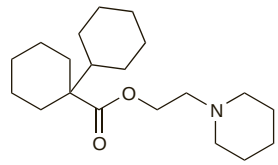
Дигексиверина Гидрохлорид

$C_{20}H_{35}NO_2$,HCl = 358.0.

CAS — 561-77-3 (dihexyverine); 5588-25-0 (dihexyverine hydrochloride).

ATC — A03AA08.

ATC Vet — QA03AA08.



(dihexyverine)

Profile

Dihexyverine hydrochloride is an antimuscarinic with effects similar to those of atropine (p.1219). It has been given in the symptomatic treatment of gastrointestinal spasm.

Preparations

Proprietary Preparations (details are given in Part 3)

Fr.: Spasmodex†.

Dihydroxyaluminum Sodium Carbonate

Aluminium Sodium Carbonate Hydroxide; Carbonato sódico de dihidroxialuminio; Dihidroksialüminyum Sodyum Karbonat; Dihydroksialuminiumnatriumkarbonaatti; Dihydroxialuminiinatrii Carbonas; Dihydroxialuminiumnatriumkarbonat; Dihydroxyaluminium Sodium Carbonate. Sodium (carbonato)dihydroxyaluminate(1-).

Дигидрооксиалюминия Натрия Карбонат

CH_2AlNaO_5 = 144.0.

CAS — 41342-54-5 (carbaldrate); 12011-77-7 (dihydroxyaluminium sodium carbonate); 16482-55-6 (dihydroxyaluminium sodium carbonate).

ATC — A02AB04.

ATC Vet — QA02AB04.

NOTE. The name Carbaldrate (*rINN*) has been applied to (CH_2AlNaO_5,*n*H_2O), a form of sodium (carbonato)dihydroxyaluminate(1-) hydrate.

Pharmacopoeias. In *US*.

USP 31 (Dihydroxyaluminum Sodium Carbonate). A fine white odourless powder. It loses not more than 14.5% of its weight on drying. Practically insoluble in water and in organic solvents;