

for up to 12 weeks. For maintenance, 1.5 g twice daily is recommended, adjusted according to response up to a maximum of 6 g daily.

In the USA, licensed doses in children aged 5 to 17 years are 750 mg three times daily by mouth, or 2.25 g three times daily; treatment may be continued for up to 8 weeks.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Benoquin; **Austral.:** Colazide; **Cz.:** Colazide†; **Denm.:** Premid; **Ital.:** Balzide; **Norw.:** Colazid; **UK:** Colazide; **USA:** Colazal.

Multi-ingredient: **Swed.:** Colazid.

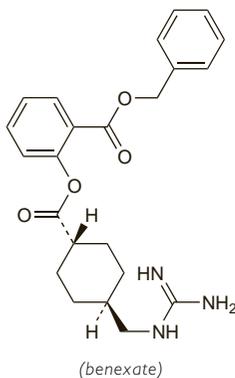
Benexate Hydrochloride (rINN)

Béxexate, Chlorhydrate de; Benexati Hydrochloridum; Hidrocloruro de benexato. Benzyl salicylate *trans*-4-(guanidinomethyl)cyclohexanecarboxylate hydrochloride.

Бенексат Гидрохлорид

$C_{22}H_{27}N_3O_4 \cdot HCl = 445.9$.

CAS — 78718-52-2 (benexate); 78718-25-9 (benexate hydrochloride); 91574-91-3 (benexate hydrochloride beta-dex).



Profile

Benexate hydrochloride is a mucosal protectant that has been used in the management of peptic ulcer disease. The β -cyclodextrin clathrate, benexate hydrochloride betadex, has been given in an oral dose of 400 mg twice daily.

Preparations

Proprietary Preparations (details are given in Part 3)

Jpn: Uligut.

Bisacodyl (BAN, rINN)

Bisacodilo; Bisacodylum; Bisakodil; Bisakodilisi; Bisakodyli; Bisakodylli; Biszakodil. 4,4'-(2-Pyridylmethylene)di(phenyl acetate).

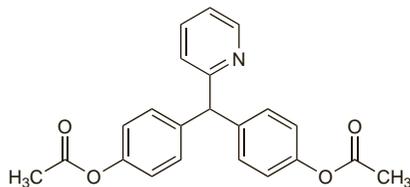
Бисакодил

$C_{22}H_{19}NO_4 = 361.4$.

CAS — 603-50-9.

ATC — A06AB02; A06AG02.

ATC Vet — QA06AB02; QA06AG02.



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

Ph. Eur. 6.2 (Bisacodyl). A white or almost white crystalline powder. Practically insoluble in water; sparingly soluble in alcohol; soluble in acetone. It dissolves in dilute mineral acids. Protect from light.

USP 31 (Bisacodyl). A white to off-white crystalline powder. Practically insoluble in water; soluble in benzene; soluble 1 in 210 of alcohol, 1 in 2.5 of chloroform, and 1 in 275 of ether; sparingly soluble in methyl alcohol.

Bisacodyl Tannex (BANM, USAN, rINN)

CAS — 1336-29-4.

ATC — A06AB02; A06AG02.

ATC Vet — QA06AB02; QA06AG02.

Adverse Effects

Bisacodyl and other stimulant laxatives may cause abdominal discomfort such as colic or cramps. Prolonged use or overdosage can result in diarrhoea with excessive loss of water and electrolytes, particularly potassium; there is also the possibility of developing an atonic non-functioning colon. Hypersensitivity reactions, including angioedema and anaphylactoid reactions, have been reported rarely. When given rectally, bisacodyl sometimes causes irritation and may cause proctitis or sloughing of the epithelium. To avoid gastric irritation bisacodyl tablets are enteric-coated.

Precautions

As with other laxatives, prolonged use should be avoided. Bisacodyl should not be given to patients with intestinal obstruction or acute abdominal conditions such as appendicitis; care should also be taken in patients with inflammatory bowel disease. It should not be used in patients with severe dehydration. The suppositories should preferably be avoided in patients with anal fissures, proctitis, or ulcerated haemorrhoids.

Handling. Inhalation of bisacodyl powder and contact with eyes, skin, and mucous membranes should be avoided.

Pharmacokinetics

On oral or rectal use bisacodyl is converted to the active desacetyl metabolite bis(*p*-hydroxyphenyl)-pyridyl-2-methane by intestinal and bacterial enzymes. Absorption from the gastrointestinal tract is minimal with enteric-coated tablets or suppositories; the small amount absorbed is excreted in the urine as the glucuronide. Bisacodyl is mainly excreted in the faeces.

Uses and Administration

Bisacodyl is a diphenylmethane stimulant laxative (p.1693) used for the treatment of constipation (p.1693) and for bowel evacuation before investigational procedures or surgery. Its action is mainly in the large intestine and it is usually effective within 6 to 12 hours after oral doses, within 15 to 60 minutes after rectal use by suppository, and within 5 to 20 minutes when given as an enema. Bisacodyl tablets should be swallowed whole and should not be taken within 1 hour of milk or antacids.

For constipation, bisacodyl is given in usual doses of 5 to 10 mg daily as enteric-coated tablets given at night or 10 mg as a suppository or enema given in the morning. Oral doses of 10 to 20 mg are given for complete bowel evacuation, followed by 10 mg as a suppository the next morning. For doses in children, see below.

A complex of bisacodyl with tannic acid (bisacodyl tannex) has been given with a barium sulfate enema before radiographic examination of the colon.

Administration in children. For constipation, the following oral doses of bisacodyl are recommended for children, to be taken at night:

- 4 to 10 years: 5 mg
- over 10 years: 5 to 10 mg

Alternatively, the following rectal doses are recommended, to be inserted in the morning:

- under 10 years: 5 mg
- over 10 years: 10 mg

The *BNFC* gives similar doses, but limits the use of suppositories in children to those aged over 2 years.

For bowel clearance before surgery or radiological investigation, the following doses are recommended:

- 4 to 10 years: 5 mg orally the night before, followed by 5 mg as a suppository the next morning
- over 10 years: 10 to 20 mg orally the night before, followed by 10 mg as a suppository the next morning

The *BNFC* gives similar doses but allows for the use of oral doses for 2 nights before the procedure, followed, if necessary, by the rectal dose 1 hour before the procedure.

Preparations

BP 2008: Bisacodyl Suppositories; Gastro-resistant Bisacodyl Tablets;

USP 31: Bisacodyl Delayed-release Tablets; Bisacodyl Rectal Suspension; Bisacodyl Suppositories.

Proprietary Preparations (details are given in Part 3)

Arg.: Dulcolax; Laxamin; Modaton; Tractoduo; **Austral.:** Bisalax; Dulcolax; **Austria:** Dulcolax; Laxbene; **Belg.:** Carters; Dulcolax; Henafurine; Muci-

num; Nosik-Lax; Purgo-Pil; **Braz.:** Bisalax; Cronoplex; Dislax†; Dulcolax; Fi-deine; Islax; Plesona†; **Canad.:** Alophen; Bisalax; Carters Little Pills; Correctol; Dulcolax; Feen-A-Mint†; Gentlax; Laxcodyl†; Soflax EX; **Chile:** Alysax; **Cz.:** Fenolax; Pyriax†; Stadalax; **Denm.:** Dulcolax; Perilax; Toilax; **Fin.:** Metalax; Toilax; **Fr.:** Contalax; Dulcolax; **Ger.:** Agarolletten; Bekunis Bisacodyl; Bisco-Zitron; Drix Bisacodyl; Dulcolax; Flonsan N; Laxagetten; Laxamin N†; Laxans-ratiopharm; Laxoberal; Laxoberal Bisalax; Laxysat Burger; Manienbader Pillen N; Mediolax; Pyriax; Stadalax†; Tempolax; Tirgon; Vircoco-Abfuhr-Perlen†; **Gr.:** Dulcolax; Flonsan N; **Hong Kong:** Dulcolax; Marcholax; **Hung.:** Dulcolax; Stadalax; **India:** Bo-Lax; Dulcolax; Julax; Julax-M†; **Indon.:** Bicolax; Dulcolax; Laxacol; Laxamex; Stolax; Dulcolax; Toilax; **Israel:** Atzirul X; Contalax; Laxadin; **Ital.:** Alaxa; Conifetto CM†; Dulcolax; Normalene; Stixenil; Verecolene CM; **Malaysia:** Beacolux†; Dulcolax; **Mex.:** Dulcolax; **Neth.:** Bekunis Bisacodyl; Dulcolax; Kruidvat Laxeertabletten; Nouilax; Toilax; Trekpleister Laxeerdagees†; **Norw.:** Dulcolax; Toilax; **NZ:** Dulcolax; Fleet Laxative; **Philipp.:** Dulcolax; Vesilax; **Port.:** Dulcolax; Moderlax; **Rus.:** Dulcolax (Дульколак); **S.Afr.:** Dulcolax; Megalax†; Perilax; **Singapore:** Dulcolax; **Spain:** Dulco Laxo; **Swed.:** Dulcolax; Toilax; **Switz.:** Bekunis Dragees; Demolaxin; Dulcolax; Muxol; Prontolax; Tavolax nouvelle formule; **Thai.:** Conlax; Dulcolax; Emulax; Gencolax; Kadolax; Laxcodyl; Laxitab; **Vacolax; Turk.:** Bisakol; Sekolaks; **UAE:** Laxocodyl; **UK:** Biolax; Dulcolax; Entrolax; **USA:** Alophen; Bisalax; Correctol; Doxidax; Dulcolax; Evac-Q-Tabs; Ex-Lax Ultra; Feen-A-Mint; Fleet Bisacodyl; Fleet Laxative; Gentlax; Modane; **Venez.:** Dulcolan.

Multi-ingredient: **Arg.:** En-Ga-Lax; Laxicon; Nigalax; **Austral.:** Coloxyl; Durolax X-Pack†; Go Kit; Go Kit Plus†; **Austria:** Laxbene; Prepacol; Purgazen; Purigo†; **Belg.:** Prepacol; Softene; **Canad.:** Bicholate; Extra Strong Formula 12†; Fruitatives†; Gentlax S; Roylac Kit; **Chile:** Laxogeno; **Cz.:** Prepacol; **Fr.:** Prepacol; **Ger.:** Potosilo N; Prepacol; **Gr.:** Flonsan; **Hung.:** Laxbene; **NZ:** Coloxyl; **Port.:** Bekunis; **Spain:** Bekunis Complex; Boldolax-in†; **Thai.:** Bisalax; **Turk.:** Bekunis; **USA:** Dulcolax Bowel Prep Kit; Fleet Prep Kit No. 1; Fleet Prep Kit No. 2; Fleet Prep Kit No. 3; HalfLyte†; X-Prep Bowel Evacuant Kit-1.

Bismuth Compounds

Bismuto, compuestos de.

Висмут Соединения

Bismuth compounds have been used for their astringent and antidiarrhoeal properties in a variety of gastrointestinal disorders, and have been applied topically in skin disorders and anorectal disorders such as haemorrhoids. Certain salts are active against *Helicobacter pylori* and are used in the treatment of peptic ulcer disease.

Bismuth Aluminate (USAN)

Aluminato de bismuto; Aluminum Bismuth Oxide.

Алюминат Висмута

$Bi_2(Al_2O_4)_3 \cdot 10H_2O = 952.0$.

CAS — 12284-76-3 (anhydrous bismuth aluminate).

Pharmacopoeias. In *Chin.* and *Fr.*

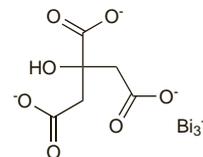
Bismuth Citrate

Citrato de bismuto.

Цитрат Висмута

$Bi_2C_6H_5O_7 = 398.1$.

CAS — 813-93-4.



NOTE. Do not confuse with bismuth subcitrate potassium (p.1711) or tripotassium dicitratobismuthate (colloidal bismuth subcitrate, p.1711).

Pharmacopoeias. In *US*.

USP 31 (Bismuth Citrate). A white, amorphous or crystalline powder. Insoluble in water and in alcohol; soluble in dilute ammonia solution and in solutions of alkali citrates. Store in airtight containers. Protect from light. Prevent exposure to temperatures above 40°.

Bismuth Oxide

Bismuth Trioxide; Óxido de bismuto.

Оксид Висмута

$Bi_2O_3 = 466.0$.

CAS — 1304-76-3.

