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55. Rodríguez-Roisin R. COPD exacerbations 5: management. *Thorax* 2006; **61:** 535–44.
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58. Niewoehner DE, *et al.*. Effect of systemic glucocorticoids on exacerbations of chronic obstructive pulmonary disease. *N Engl J Med* 1999; **340:** 1941–7.
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Acefylline Piperazine *(BAN, rINN)*

Acefilina piperazina; Acéfylline Pipérazine; Acefyllinum Piperazinum; Acepifylline; Piperazine Theophylline Ethanoate. Piperazine bis(theophyllin-7-ylacetate) (1:1).

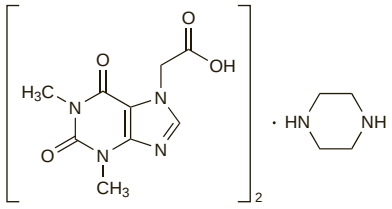
Ацефиллин Пиперазин

$(C_9H_{10}N_4O_4)_2,C_4H_{10}N_2$ = 562.5.

CAS — 18833-13-1; 18428-63-2.

ATC — R03DA09.

ATC Vet — QR03DA09.



Profile

Acefylline piperazine is a derivative of theophylline (p.1140) that has been used for its bronchodilator effects. It is not converted to theophylline in the body.

Preparations

Proprietary Preparations (details are given in Part 3)
India: Etophylate†; ***Indon.:*** Etaphylline.

Multi-ingredient: ***India:*** Cadiphylate.

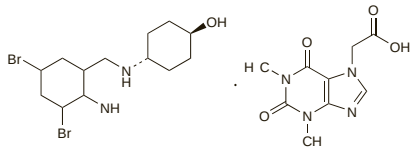
Ambroxol Acefyllinate *(BANM, rINNM)*

Acebrofylline; Acebrophylline; Acefilinato de ambroxol; Ambroxol Acéfylline; Ambroxoli Acefyllinas.

Амброксола Ацефиллинат

$C_{13}H_{18}Br_2N_2O,C_9H_{10}N_4O_4$ = 616.3.

CAS — 96989-76-3.



Profile

Ambroxol acefyllinate is a xanthine derivative that is used as a bronchodilator. It is given in an oral dose of 100 mg twice daily. For doses in children see below.

Administration in children. Ambroxol acefyllinate can be used as a bronchodilator in children. Children from 1 to 6 years of age may be given an oral dose of 25 mg twice daily, and children from 6 to 12 years, 50 mg twice daily.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Dogistin†; Mucomex†; ***Braz.:*** Brismucol; Brondilat; Bronfilil; Cebronfilina; Expecdilat; Filinar; Teomuc; ***Ital.:*** Ambromucil; Broncomnes; Surfolase; ***Mex.:*** Brismucol; ***Port.:*** Surfolase†; Tusolven†; ***Venez.:*** Brixilon; Bronilis.

Aminophylline *(BAN, pINN)*

Aminofilin; Aminofilina; Aminofylin; Aminofylliini; Aminofyllin; Aminophyllinum; Euphyllinum; Metaphyllin; Teofilinas-etilendiaminas; Teofillinetiléndiamin; Teofylliinetyleenidiamiini; Teofyllinetylendiamin; Theophyllaminum; Theophylline and Ethylenediamine; Theophylline Ethylenediamine Compound; Théophylline-éthylènediamine; Theophyllinum et ethylenediaminum. A mixture of theophylline and ethylenediamine (2:1), its composition approximately corresponding to the formula below.

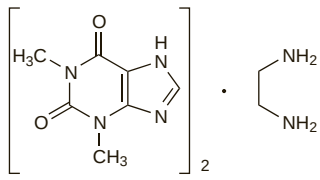
Аминофиллин

$(C_7H_8N_4O_2)_2,C_2H_4(NH_2)_2$ = 420.4.

CAS — 317-34-0 (anhydrous aminophylline).

ATC — R03DA05.

ATC Vet — QR03DA05.



Pharmacopoeias. In *Eur.* (see p.vii), *Int.*, *US*, and *Viet.* Some pharmacopoeias include anhydrous and hydrated aminophylline in one monograph. Some pharmacopoeias do not specify the hydration state.

Ph. Eur. 6.2 (Theophylline-ethylenediamine; Aminophylline BP 2008). It contains 84.0 to 87.4% of anhydrous theophylline and 13.5 to 15.0% of anhydrous ethylenediamine. A white or slightly yellowish powder, sometimes granular. Freely soluble in water (the solution becomes cloudy through absorption of carbon dioxide); practically insoluble in dehydrated alcohol. Store in airtight containers. Protect from light.

USP 31 (Aminophylline). It is anhydrous or contains not more than two molecules of water of hydration. It contains not less than 84.0 and not more than 87.4% of anhydrous theophylline. It consists of white or slightly yellowish granules or powder, having a slight ammoniacal odour. Upon exposure to air it gradually loses ethylenediamine and absorbs carbon dioxide with the liberation of theophylline. One g dissolves in 25 mL of water to give a clear solution; 1 g dissolved in 5 mL of water crystallises upon standing, but redissolves when a small amount of ethylenediamine is added; insoluble in alcohol and in ether. Its solutions are alkaline to litmus. Store in airtight containers.

Aminophylline Hydrate *(BANM, pINNM)*

Aminofilina dwuwodna; Aminofilina hidratada; Aminofylin hydratovaný; Aminophylline, Hydrate d'; Aminophyllini Hydratum; Aminophyllinum Dihydricum; Aminophyllinum Hydricum; Teofylliinietyleenidiamiinihydraatti; Teofyllinetylendiaminhydrat; Théophylline-éthylènediamine hydratée; Theophyllinum et ethylenediaminum hydricum.

Аминофиллина Гидрат

$(C_7H_8N_4O_2)_2,C_2H_4(NH_2)_2,2H_2O$ = 456.5.

CAS — 49746-06-7 (aminophylline dihydrate).

ATC — R03DA05.

ATC Vet — QR03DA05.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Jpn*, *US*, and *Viet.* Some pharmacopoeias include anhydrous and hydrated aminophylline in one monograph. Some pharmacopoeias do not specify the hydration state.

Ph. Eur. 6.2 (Theophylline-ethylenediamine Hydrate; Aminophylline Hydrate BP 2008). It contains 84.0 to 87.4% of anhydrous theophylline and 13.5 to 15.0% of anhydrous ethylenediamine. A white or slightly yellowish powder, sometimes granular. Freely soluble in water (the solution becomes cloudy through absorption of carbon dioxide); practically insoluble in dehydrated alcohol. Store in well-filled airtight containers. Protect from light.

USP 31 (Aminophylline). It is anhydrous or contains not more than two molecules of water of hydration. It contains not less than 84.0 and not more than 87.4% of anhydrous theophylline. It consists of white or slightly yellowish granules or powder, having a slight ammoniacal odour. Upon exposure to air it gradually loses ethylenediamine and absorbs carbon dioxide with the liberation of theophylline. One g dissolves in 25 mL of water to give a clear solution; 1 g dissolved in 5 mL of water crystallises upon standing, but redissolves when a small amount of ethylenediamine is added; insoluble in alcohol and in ether. Its solutions are alkaline to litmus. Store in airtight containers.

Incompatibility. Aminophylline solutions should not be allowed to come into contact with metals.

Solutions of aminophylline are alkaline and if the pH falls below 8, crystals of theophylline will deposit.[1] Drugs known to be unstable in alkaline solutions, or that would lower the pH below the critical value, should not be mixed with aminophylline.

1. Edward M. pH—an important factor in the compatibility of additives in intravenous therapy. *Am J Hosp Pharm* 1967; **24:** 440–9.

Adverse Effects, Treatment, and Precautions

As for Theophylline, p.1140. Hypersensitivity has been associated with the ethylenediamine content.

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

Interactions

As for Theophylline, p.1142.

Pharmacokinetics

Aminophylline, a complex of theophylline with ethylenediamine, readily liberates theophylline in the body. The pharmacokinetics of theophylline are discussed on p.1145.

◊ Studies in healthy subjects suggested that ethylenediamine does not affect the pharmacokinetics of theophylline after oral or intravenous dosage.[1,2]

1. Aslaksen A, *et al.* Comparative pharmacokinetics of theophylline and aminophylline in man. *Br J Clin Pharmacol* 1981; **11:** 269–73.
2. Caldwell J, *et al.* Theophylline pharmacokinetics after intravenous infusion with ethylenediamine or sodium glycinate. *Br J Clin Pharmacol* 1986; **22:** 351–5.

Uses and Administration

Aminophylline has the actions and uses of theophylline (see p.1146) and is used similarly as a bronchodilator in the management of asthma (p.1108) and chronic obstructive pulmonary disease (p.1112). Aminophylline is also used to relieve neonatal apnoea (p.1118). It was formerly used as an adjunct in the treatment of heart failure, and may occasionally have a role in patients with this condition who are also suffering from obstructive airways disease. Aminophylline is usually preferred to theophylline when greater solubility in water is required, particularly in intravenous formulations.

Aminophylline may be given in the anhydrous form or as the hydrate, and doses may be expressed as either; aminophylline hydrate 1.09 mg is equivalent to about

1 mg of aminophylline. The USP 31 specifies that aminophylline preparations should be labelled with respect to their anhydrous *theophylline* content. As the pharmacokinetics of theophylline are affected by a number of factors including age, smoking, disease, diet, and drug interactions, the dose of aminophylline must be carefully individualised and serum-theophylline concentrations monitored (see Uses and Administration of Theophylline, p.1146).

In the management of **acute severe bronchospasm**, aminophylline may be given intravenously by slow injection or infusion. To reduce adverse effects, intravenous aminophylline should not be given at a rate greater than 25 mg/minute. In adults who have not been taking aminophylline, theophylline, or other xanthine-containing medication, a loading dose of 5 mg/kg ideal (lean) body-weight or 250 to 500 mg of aminophylline may be given intravenously over 20 to 30 minutes by slow injection or infusion, followed by a maintenance infusion dose of 500 micrograms/kg per hour. Older patients and those with cor pulmonale, heart failure, or liver disease may require lower maintenance doses; smokers often need higher maintenance doses. A loading dose may not be considered necessary unless the patient's condition is deteriorating.

Intravenous aminophylline is best avoided in patients already taking theophylline, aminophylline, or other xanthine-containing medication but, if considered necessary, the serum-theophylline concentration should first be assessed and the initial loading dose should be calculated on the basis that each 600 micrograms/kg of aminophylline (equivalent to 500 micrograms/kg theophylline) will increase serum-theophylline concentration by 1 microgram/mL.

In the management of **chronic bronchospasm** aminophylline may be given orally as modified-release preparations; a usual dose is aminophylline hydrate 225 to 450 mg twice daily. Therapy should start with the lower dose and be increased as appropriate. Retitration of the dosage is required if the patient is changed from one modified-release preparation to another as the bioavailability of modified-release aminophylline preparations may vary.

For doses of aminophylline used in children, see Administration in Children, below.

Intramuscular injection of aminophylline causes intense local pain and is not recommended.

Aminophylline has also been used as the hydrochloride.

Administration. ***RECTAL ADMINISTRATION.*** Absorption from aminophylline suppositories is erratic and this dose form has been associated with toxicity, hence the warnings that suppositories should not be used, especially in children. In the UK suppositories are no longer readily available and one hospital wishing to use the rectal route for apnoea in premature infants (see Neonatal Apnoea, p.1118) achieved therapeutic plasma-theophylline concentrations with a specially formulated rectal gel.[1]

1. Cooney S, *et al*. Rectal aminophylline gel in treatment of apnoea in premature newborn babies. *Lancet* 1991; **337:** 1351.

Administration in children. Aminophylline may be given intravenously, by slow injection or infusion, to manage **acute severe bronchospasm** in children. Doses should be calculated using ideal or lean body-weight. In children who have not been taking aminophylline, theophylline or other xanthine-containing medicine, UK licensed product information recommends a loading dose of 5 mg/kg given by slow injection or infusion over 20 to 30 minutes. Initial maintenance dose ranges are:

- 6 months up to 10 years of age: 1 mg/kg per hour
- 10 to 16 years of age: 800 micrograms/kg per hour

Although unlicensed in the UK for use in children under 6 months, the *BNFC* allows a dose of 1 mg/kg per hour from 1 month of age. Children aged from 16 years and above may be given adult doses, see Uses and Administration, above. Serum-theophylline concentrations should be used to guide further dose adjustments.

Children who are already receiving theophylline, aminophylline or other xanthine-containing medicines, should not normally receive intravenous aminophylline unless serum-theophylline concentration is available to guide dosage. Loading doses are based on the expectation that each 500 micrograms/kg lean body-weight of theophylline will result in a 1-microgram/mL increase in serum-theophylline concentration.

Oral modified-release preparations are given to children with a body-weight over 40 kg in the long-term management of **chronic bronchospasm**. An initial dose of 225 mg twice daily may be given if the child has not previously received xanthine preparations, increased after 1 week to 450 mg twice daily according to serum-theophylline concentrations. Different modified-release preparations are not considered interchangeable.

Aminophylline may also be used in the management of **neonatal apnoea** (see p.1118). Although the injection is unlicensed in the UK in children under 6 months of age, the *BNFC* recommends an initial dose of 6 mg/kg by intravenous injection over 20 minutes. This is followed by 2.5 mg/kg every 12 hours, increased if necessary to 3.5 mg/kg every 12 hours. The plasma theophylline concentration for optimum response in neonatal apnoea is 8 to 12 mg/litre. For further information on the dosage of theophylline itself in neonates, see Administration in Infants, p.1147.

Erectile dysfunction. For reference to the use of a cream containing aminophylline, isosorbide dinitrate, and codergocrine mesilate in the treatment of erectile dysfunction, see under Glyceryl Trinitrate, p.1298.

Methotrexate neurotoxicity. For reference to the use of aminophylline or theophylline to relieve the acute neurotoxicity of methotrexate, see Other Drugs, under Treatment of Adverse Effects, p.747.

Motor neurone disease. A study[1] in 25 patients with amyotrophic lateral sclerosis (see p.2380) found that aminophylline improved the endurance of respiratory muscles and increased the handgrip strength of skeletal muscles; it may have some potential therapeutic benefit in such patients.

1. Berto MC, *et al*. Acute action of aminophylline in patients with amyotrophic lateral sclerosis. *Acta Neurol Scand* 2007; **115:** 301–5.

Reduction of body fat. Cosmetic aminophylline cream has been promoted for its supposed ability to remove fat ('cellulite') from the thighs.[1] Concern has been raised about the potential for topical sensitisation.[2]

1. Dickinson BI, Gora-Harper ML. Aminophylline for cellulite removal. *Ann Pharmacother* 1996; **30:** 292–3.
2. Simon PA. Comment: aminophylline-containing cream. *Ann Pharmacother* 1996; **30:** 1341.

Preparations

BP 2008: Aminophylline Injection; Aminophylline Tablets;
USP 31: Aminophylline Delayed-release Tablets; Aminophylline Injection; Aminophylline Oral Solution; Aminophylline Rectal Solution; Aminophylline Suppositories; Aminophylline Tablets.

Proprietary Preparations (details are given in Part 3)
Arg.: Cardirenal†; Fadafilina; Larjanfilina; ***Austria:*** Euphyllin; Mundiphyllin†; ***Braz.:*** Aminoima; Aminoliv; Asmafin; Asmapen; Asmodrin; Asmoquinol; Minoton; Unifilin; ***Canad.:*** Phyllocontin; ***Chile:*** Cardiomin†; ***Cz.:*** Pharophyllin†; Syntophyllin; ***Denm.:*** Teofylamin; ***Fin.:*** Aminocont; ***Ger.:*** Phyllotemp†; ***Hung.:*** Diaphyllin; ***Indon.:*** Phyllocontin; ***Irl.:*** Phyllocontin; ***Ital.:*** Aminomal; Tefamin; ***Jpn:*** Neophyllin; ***Mex.:*** Amofilin; Drafilyn-Z; ***Neth.:*** Euphyllin†; ***Port.:*** Filotempo; ***S.Afr.:*** Peterphyllin; Phyllocontin; ***Swed.:*** Teofyllamin; ***Switz.:*** Escophylline†; Phyllotemp†; ***Thai.:*** Asmalia; Fileen†; ***Turk.:*** Aminocardol; Asmafilin; Carena; ***UK:*** Amnivent†; Phyllocontin; ***USA:*** Truphylline†; ***Venez.:*** Broncophilina.

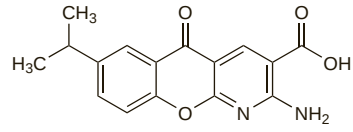
Multi-ingredient: ***Austria:*** Asthma-Hilfe; Limptar; Myocardon; ***Braz.:*** Alergo Filinal; Alergotox Expectorante†; Alergotox†; Dispneitrat; ***Ger.:*** Limptar†; ***Hong Kong:*** Asmeton; ***Mex.:*** Isobutil†; Paliatil; ***Port.:*** Anti-Asmatico; ***S.Afr.:*** Diphenamill†; Genasma; Lotussin Expectorant†; Natrophylline Compound; Repasma; ***Thai.:*** Asmeton†; ***USA:*** Emergent-Ez; ***Venez.:*** Fedratal†.

Amlexanox *(BAN, USAN, rINN)*

AA-673; Amlexanoxo; Amlexanoxum; Amoxanox; CHX-3673. 2-Amino-7-isopropyl-5-oxo-5*H*-[1]benzopyrano[2,3-*b*]pyridine-3-carboxylic acid.

Амлексанокс

$C_{16}H_{14}N_2O_4$ = 298.3.
CAS — 68302-57-8.
ATC — A01AD07; R03DX01.
ATC Vet — QA01AD07; QR03DX01.



Profile

Amlexanox has a stabilising action on mast cells resembling that of sodium cromoglicate (p.1136) and also acts as a leukotriene inhibitor. It is given orally in the management of asthma (p.1108) and for allergic rhinitis (p.565); a dose of 25 or 50 mg three times daily has been suggested. Amlexanox is also given as a metered-dose nasal spray for allergic rhinitis.

Amlexanox is also applied as a 5% oral paste four times daily in the management of aphthous ulcers (see Mouth Ulceration, p.1700). A 2-mg biodegradable oral disc designed to deliver amlexanox locally is also available.

Preparations

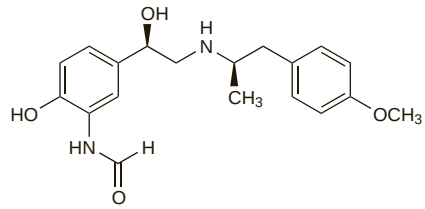
Proprietary Preparations (details are given in Part 3)
Jpn: Solfa; ***Neth.:*** Miraftil; ***USA:*** Aphthasol.

Arformoterol Tartrate *(USAN, rINNM)* ⊗

Arformotérol, Tartrate d'; Arformoteroli Tartras; *R,R*-Formoterol Tartrate; Tartrato de arformoterol. (-)-*N*-[2-Hydroxy-5-((1*R*)-1-hydroxy-2-{[(1*R*)-2-(4-methoxyphenyl)-1-methylethyl]amino}ethyl)phenyl]formamide hydrogen (2*R*,3*R*)-2,3-dihydroxybutanedioate.

Арформотерола Тартрат

$C_{19}H_{24}N_2O_4,C_4H_6O_6$ = 494.5.
CAS — 67346-49-0 (arformoterol); 200815-49-2 (arformoterol tartrate).



(arformoterol)

Profile

Arformoterol is the *R,R*-enantiomer of the beta$_2$-adrenoceptor agonist formoterol (p.1122) and has similar properties. Arformoterol is a long-acting selective beta$_2$ agonist which is used as a bronchodilator in the management of chronic obstructive pulmonary disease (p.1112). It is given as the tartrate, but doses are described in terms of the base; 22 micrograms of arformoterol tartrate is equivalent to about 15 micrograms of arformoterol. Given as a nebulised solution, a usual inhaled dose of arformoterol is 15 micrograms given every 12 hours.

◊ References.

1. Lötvall J, *et al*. The effect of formoterol over 24 h in patients with asthma: the role of enantiomers. *Pulm Pharmacol Ther* 2005; **18:** 109–13.
2. Anonymous. Arformoterol (Brovana) for COPD. *Med Lett Drugs Ther* 2007; **49:** 53–5.
3. Baumgartner RA, *et al*. Nebulized arformoterol in patients with COPD: a 12-week, multicenter, randomized, double-blind, double-dummy, placebo- and active-controlled trial. *Clin Ther* 2007; **29:** 261–78.
4. Matera MG, Cazzola M. Ultra-long-acting β -adrenoceptor agonists: an emerging therapeutic option for asthma and COPD? *Drugs* 2007; **67:** 503–15.

Preparations

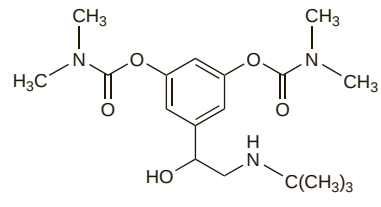
Proprietary Preparations (details are given in Part 3)
USA: Brovana.

Bambuterol Hydrochloride *(BANM, rINNM)* ⊗

Bambutérol, chlorhydrate de; Bambuterol-hidroklorid; Bambuterol-hydrochlorid; Bambuterolhydroklorid; Bambuteroli hydrochloridum; Bambuterolihydrokloridi; Bambuterolio hidrochloridas; Hidrocloruro de bambuterol; KWD-2183. (*RS*)-5-(2-*tert*-Butylamino-1-hydroxyethyl)-*m*-phenylene bis(dimethylcarbamate) hydrochloride.

Бамбутерола Гидрохлорид

$C_{18}H_{29}N_3O_5$,HCl = 403.9.
CAS — 81732-65-2 (bambuterol); 81732-46-9 (bambuterol monohydrochloride).
ATC — R03CC12.
ATC Vet — QR03CC12.



(bambuterol)

Pharmacopoeias. In *Eur.* (see p.vii).
Ph. Eur. 6.2 (Bambuterol Hydrochloride). A white or almost white crystalline powder. It exhibits polymorphism. Freely soluble in water; soluble in alcohol.

Adverse Effects and Precautions

As for Salbutamol, p.1131. Bambuterol is not recommended for patients with severe hepatic impairment as its metabolism would be unpredictable. The dose of bambuterol should be reduced in