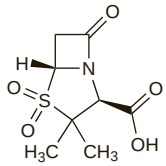
Sulbactam *(BAN, rINN)*

CP-45899; Sulbactamum; Sulbaktaami; Sulbaktam. Penicillanic acid 1,1-dioxide; (2*S*,5*R*)-3,3-Dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide.

Сульбактам

$C_8H_{11}NO_5S$ = 233.2.
CAS — 68373-14-8.
ATC — J01CG01.
ATC Vet — QJ01CG01.



Sulbactam Sodium *(BANM, USAN, rINNM)*

CP-45899-2; Natrii Sulbactamum; Sulbactam sódico; Sulbactam sodique; Sulbactamum natricum; Sulbaktaaminatrium; Sulbaktam sodná sůl; Sulbaktam sodowy; Sulbaktamnatrium.

Натрий Сульбактам

$C_8H_{10}NNaO_5S$ = 255.2.
CAS — 69388-84-7.
ATC — J01CG01.
ATC Vet — QJ01CG01.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Jpn*, and *US*.
Ph. Eur. 6.2 (Sulbactam Sodium). A white or almost white, hygroscopic, crystalline powder. Freely soluble in water; very slightly soluble in alcohol; sparingly soluble in ethyl acetate. It is freely soluble in diluted acids. A 5.0% solution in water has a pH of 4.5 to 7.2; if the substance is sterile: 5.2 to 7.2. Store in airtight containers.
USP 31 (Sulbactam Sodium). A white to off-white crystalline powder. It contains not less than 886 micrograms and not more than 941 microgram of sulbactam per mg, calculated on the anhydrous basis. Freely soluble in water and in dilute acid; sparingly soluble in acetone, in chloroform, and in ethyl acetate. Store in airtight containers.

Pivsulbactam *(BAN)*

CP-47904; Sulbactam Pivoxil *(USAN)*. Pivaloyloxymethyl penicillanate 1,1-dioxide.

Пивсульбактам

$C_{14}H_{21}NO_7S$ = 347.4.
CAS — 69388-79-0.

Profile
Sulbactam is a penicillanic acid sulfone with beta-lactamase inhibitory properties. It is active against Neisseriaceae and *Acinetobacter baumanii*, but generally has only weak antibacterial activity against other organisms. It is an irreversible inhibitor of many plasmid-mediated and some chromosomal beta-lactamases and has a similar spectrum of beta-lactamase inhibition to clavulanic acid (p.250), although it is regarded as less potent. Sulbactam can therefore enhance the activity of penicillins and cephalosporins against many resistant strains of bacteria.

It is given with ampicillin (p.204) in the treatment of infections where beta-lactamase production is suspected. Sulbactam is poorly absorbed from the gastrointestinal tract and is given by injection as the sodium salt. The pharmacokinetics of parenteral sulbactam and ampicillin are similar. For oral use the mutual prodrug sultamicillin (p.344) is available in some countries. Sulbactam is also given orally as the pivoxil derivative, pivsulbactam, with amoxicillin. Sulbactam has also been given with cefoperazone.

◊ References.

1. Campoli-Richards DM, Brogden RN. Sulbactam/ampicillin: a review of its antibacterial activity, pharmacokinetic properties, and therapeutic use. *Drugs* 1987; **33:** 577–609.
2. Payne DJ, *et al.* Comparative activities of clavulanic acid, sulbactam, and tazobactam against clinically important β-lactamases. *Antimicrob Agents Chemother* 1994; **38:** 767–72.
3. Nicolas-Chanoine MH. Inhibitor-resistant β-lactamases. *J Antimicrob Chemother* 1997; **40:** 1–3.
4. Lee NLS, *et al.* β-Lactam antibiotic and β-lactamase inhibitor combinations. *JAMA* 2001; **285:** 386–8.
5. Lode H. Role of sultamicillin and ampicillin/sulbactam in the treatment of upper and lower bacterial respiratory tract infections. *Int J Antimicrob Agents* 2001; **18:** 199–209.
6. Kanra G. Experience with ampicillin/sulbactam in severe infections. *J Int Med Res* 2002; **30** (suppl 1): 20A–30A.
7. Rafailidis PI, *et al.* Ampicillin/sulbactam: current status in severe bacterial infections. *Drugs* 2007; **67:** 1829–49.
8. Akova M. Sulbactam-containing beta-lactamase inhibitor combinations. *Clin Microbiol Infect* 2008; **14** (suppl 1): 185–8.

Breast feeding. Although sulbactam is distributed into breast milk in small amounts,[1] no adverse effects have been seen in breast-fed infants and the American Academy of Pediatrics considers that it is usually compatible with breast feeding.[2]

1. Foulds G, *et al.* Sulbactam kinetics and excretion into breast milk in postpartum women. *Clin Pharmacol Ther* 1985; **38:** 692–6.
2. American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. *Pediatrics* 2001; **108:** 776–89. Correction. *ibid.*; 1029. Also available at: http://aappolicy.aappublications.org/cgi/content/full/pediatrics%3b108/3/776 (accessed 28/05/04)

Preparations
USP 31: Ampicillin and Sulbactam for Injection.

Proprietary Preparations (details are given in Part 3)
Austria: Combactam; ***Ger.:*** Combactam; ***Turk.:*** Ampisid.

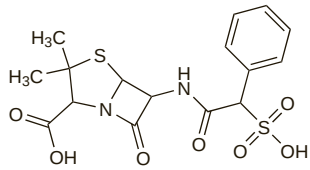
Multi-ingredient: ***Arg.:*** Aminoxidin Sulbactam; Ampi-Bis Plus; Ampigen SB; Darzitil SB; Prixin; Sulperazon†; Trifamox IBL; Unasyna; Unsayna†; ***Austria:*** Unasyn; ***Braz.:*** Combactan; Sulbacter†; Sulbamox; Trifamox; Unasyn; ***Chile:*** Sulbamox; Sulperazon; Unasyn; ***Cz.:*** Sulperazon; Unasyn; ***Fr.:*** Unacim; ***Ger.:*** Unacid; ***Gr.:*** Begalin-P; ***Hong Kong:*** Sulperazon; Unasyn; ***Hung.:*** Unasyn; ***India:*** Keftragard; Lactagard; Sulbacef; Sulbacin; Sultax; Zosul; ***Indon.:*** Fosular; Stabactam; Sulperazon; ***Israel:*** Unasyn; ***Ital.:*** Bethacil; Loricin; Unasyn; ***Jpn:*** Sulperazon†; Unasyn-S†; ***Malaysia:*** Sulbacin; Sulperazon; Unasyn; ***Mex.:*** Megamox; Trifamox IBL; Unasyna; ***Philipp.:*** Sulperazone; Unasyn; ***Pol.:*** Sulperazon; Unasyn; ***Rus.:*** Sulcef (Сульцеф); Sulperason (Сульперазон); Sultasin (Сультасин); Trifamox IBL (Трифамокс ИБЛ); Unasyn (Уназин); ***Singapore:*** Unasyn; ***Spain:*** Unasyn; ***Thai.:*** Cebactam; Cefper; Sulam; Sulcef; Sulperazon; Unasyn; ***Turk.:*** Combicid; Duobak; Duobaktam; Duocid; Nobecid; Primasef; Sulbaksit; Sulcid; Sulperazon; Sultasid; ***USA:*** Unasyn; ***Venez.:*** Ampibactan; Ampitren†; Fipexiam; Sinif; Sulperazon; Unasyn.

Sulbenicillin Sodium *(rINNM)*

Natrii Sulbenicillinum; Sulbenicilina sódica; Sulbénicilline Sodique; α-Sulfobenzylpenicillin Sodium; Sulfocillin Sodium. The disodium salt of (6*R*)-6-(2-phenyl-2-sulphoacetamido)penicillanic acid.

Натрий Сульбеницеллин

$C_{16}H_{16}N_2Na_2O_7S_2$ = 458.4.
CAS — 34779-28-7 (sulbenicillin); 41744-40-5 (sulbenicillin).
ATC — J01CA16.
ATC Vet — QJ01CA16.



(sulbenicillin)

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

Profile
Sulbenicillin sodium has actions and uses similar to those of carbenicillin sodium (p.216). It is given by intramuscular or intravenous injection or infusion.

Preparations
Proprietary Preparations (details are given in Part 3)
Indon.: Kedacillin; ***Jpn:*** Lilacillin†; ***Mex.:*** Kedacillin; ***Philipp.:*** Kedacillin.

Sulfabenzamide *(BAN, USAN, rINN)*

Sulfabensamid; Sulfabentsamidi; Sulfabenzamida; Sulfabenzamidum. *N*-Sulphanilylbenzamide.

Сульфабензамид

$C_{13}H_{12}N_2O_3S$ = 276.3.
CAS — 127-71-9.

Pharmacopoeias. In *US*.
USP 31 (Sulfabenzamide). A fine, white, practically odourless powder. Insoluble in water and in ether; soluble in alcohol, in acetone, and in sodium hydroxide 4% solution. Protect from light.

Profile
Sulfabenzamide is a sulfonamide with properties similar to those of sulfamethoxazole (p.340). It is reported to exert an optimal bacteriostatic action at pH 4.6. It is used with sulfacetamide and sulfathiazole in pessaries or a vaginal cream for the treatment of bacterial vaginosis, although its value has been questioned. The vaginal cream has also been used for the prevention of bacterial infection after cervical and vaginal surgery.

Preparations
USP 31: Triple Sulfa Vaginal Cream; Triple Sulfa Vaginal Tablets.

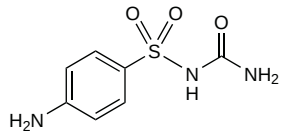
Proprietary Preparations (details are given in Part 3)
Multi-ingredient: ***Belg.:*** Sultrin†; ***Braz.:*** Vagi-Sulfa; ***Gr.:*** Sultrin; ***Irl.:*** Sultrin†; ***Philipp.:*** Sultrin; ***Port.:*** Sultrin†; ***S.Afr.:*** Sultrin; ***UK:*** Sultrin†; ***USA:*** Sultrin.

Sulfacarbamide *(BAN, rINN)*

Sulfacarbamida; Sulfacarbamidum; Sulfakarbamid; Sulfanilcarbamide; Sulfaurea; Sulphacarbamide; Sulphanilylurea; Sulphaurea; Urosulphanum. Sulphanilylurea monohydrate.

Сульфакарбамид

$C_7H_9N_3O_3S,H_2O$ = 233.2.
CAS — 547-44-4 (anhydrous sulfacarbamide); 6101-35-5 (sulfacarbamide monohydrate).



Pharmacopoeias. In *Pol*.

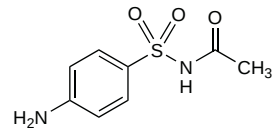
Profile
Sulfacarbamide is a sulfonamide with properties similar to those of sulfamethoxazole (p.340). It has been used in the treatment of urinary-tract infections, sometimes with other drugs.

Sulfacetamide *(BAN, rINN)*

Acetosulfaminum; Sulfacetamid; Sulfacetamida; Sulfacétamide; Sulfacetamidum; Sulfatsetamidi; Sulphacetamide. *N*-Sulphaniloylacetamide.

Сульфацетамид

$C_8H_{10}N_2O_3S$ = 214.2.
CAS — 144-80-9.
ATC — S01AB04.
ATC Vet — QS01AB04.



Pharmacopoeias. In *Int.* and *US*.
USP 31 (Sulfacetamide). A white, odourless, crystalline powder. Slightly soluble in water and in ether; soluble in alcohol; very slightly soluble in chloroform; freely soluble in dilute mineral acids and in solutions of potassium and sodium hydroxides; practically insoluble in benzene. Solutions in water are acid to litmus and sensitive to light; they are unstable when acidic or strongly alkaline. Protect from light.

Sulfacetamide Sodium *(BANM, rINNM)*

Natrii Sulfacetamidum; Soluble Sulphacetamide; Sulfacetamid sodná sůl monohydrát; Sulfacetamid sodowy; Sulfacetamida sódica; Sulfacétamide sodique; Sulfacetamidnatrium; Sulfacetamido natrio druska; Sulfacetamidum natricum; Sulfacetamidum Natricum Monohydricum; Sulfacylum; Sülfasetamid Sodyum; Sulfasetamidinatrium; Sulphacetamide Sodium; Sulphacetamidum Sodium; Szulfacetamid-nátrium.

Натрий Сульфацетамид

$C_8H_9N_2NaO_3S,H_2O$ = 254.2.
CAS — 127-56-0 (anhydrous sulfacetamide sodium); 6209-17-2 (sulfacetamide sodium monohydrate).
ATC — S01AB04.
ATC Vet — QS01AB04.

NOTE. SULF is a code approved by the BP 2008 for use on single unit doses of eye drops containing sulfacetamide sodium where the individual container may be too small to bear all the appropriate labelling information.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *US*, and *Viet.*
Ph. Eur. 6.2 (Sulfacetamide Sodium). A white or yellowish-white, crystalline powder. Freely soluble in water; slightly soluble in dehydrated alcohol. A 5% solution in water has a pH of 8.0 to 9.5. Protect from light.
USP 31 (Sulfacetamide Sodium). A white odourless crystalline powder. Soluble 1 in 2.5 of water; sparingly soluble in alcohol; practically insoluble in chloroform and in ether. A 5% solution in water has a pH of 8.0 to 9.5. Store in airtight containers. Protect from light.

Stability. When solutions of sulfacetamide sodium are heated, hydrolysis occurs forming sulfanilamide which may be deposited as crystals, especially from concentrated solutions and under cold storage conditions.

Adverse Effects, Treatment, and Precautions
As for Sulfamethoxazole, p.340.
Local application of sulfacetamide sodium to the eye may cause burning or stinging but this is rarely severe enough to require stopping treatment.