Baneocin® – powder/ointment

SANDOZ

Composition

Baneocin powder/ointment:	1 g contains
Bacitracin Zinc	250 IU
Neomycin as sulphate	5,000 IU (5 mg)

Properties and action

Baneocin is an antibiotic combination for external use only. It contains 2 highly potent (bactericidal) antibacterial agents, neomycin and bacitracin, which are synergistic.

Bacitracin is mainly active against gram-positive organisms, e. g. hemolytic streptococci, staphylococci, Clostridia, Corynebacterium diphtheriae as well as Treponema pallidum, and some gram-negative pathogens like Neisseria and Haemophilus influenzae. Its action also extends to actinomycetes and fusobacteria. Resistance to bacitracin is extremely uncommon.

Neomycin acts both against gram-positive and gram-negative pathogens, e. g. staphylococci, Proteus, Enterobacter aerogenes, Klebsiella pneumoniae, salmonellae, shigallae, Haemophilus influenzae, Pasteurella, Neisseria meningitidis, Vibrio cholerae, Bordetella pertussis, Bacillus anthracis, Corynebacterium diphtheriae, Streptococcus faecalis, Listeria monocytogenes, Escherichia coli and Mycobacterium tuberculosis. Borrelia and leptospira interrogans (L. icterohemorrhagicae) are also suppressed by it.

The combined action of the 2 drugs produces a broad-spectrum effect which does, however, not cover Pseudomonas, Nocardia, fungi and viruses.

Bacitracin and neomycin are not normally applied systemically. The local application of Baneocin powder or ointment substantially reduces the risk of sensitization to potentially required systemic antibiotics.

Baneocin is well tolerated. Tissue tolerance is excellent and there is no inactivation by secretions, blood or tissue components. If the drug is applied to large skin lesions, potential drug absorption and its consequences (see "Side effects", "Interactions", "Contraindications" and "Special warnings for safe use") should be considered.

Indications

Baneocin is effective in all infections caused by neomycin and/or bacitracin-susceptible organisms. The action of Baneocin ointment is enhanced by dressings.

Baneocin powder

– *Bacterial skin infections of limited extension, e. g.:*
Herpes simplex, Herpes zoster/varicella vesicles, wetting impetigo contagiosa, infected crural ulcers, infected eczema, bacterially infected diaper dermatitis.

– *Prevention of umbilical infections in newborns.*

– *After surgical (dermatological) procedures:*
Baneocin powder may be used as an adjuvant treatment in the postoperative care (excisions and cauterizations, treatment of rhagades, perineal rupture, episiotomies, wetting wounds and scars).

Baneocin ointment

– *Focal bacterial skin infections, e. g.:*
Furuncles, carbuncles (after operative treatment), folliculitis barbae, folliculitis profunda, suppurative hidradenitis, periporitis, paronychia.

– *Bacterial skin infections of limited extension, e. g.:*
Impetigo contagiosa, infected crural ulcers, secondarily infected eczema, secondarily infected lacerations and cuts, scalds, burns, in cosmetic surgery and skin grafting (also for prophylactic use and on dressings).

– *After major or minor surgical procedures:*
Baneocin ointment may be used as an adjuvant treatment during postoperative care.
Baneocin ointment spread on gauze strips is beneficial for directed local treatment in patients with infected body or wound cavities (e. g. infections of the outer ear canal, wounds or surgical scars left to heal by secondary intention).

Mode of application

Apply powder or ointment sparingly to the area to be treated; cover with dressing, if desirable.

Dosage

In adults and children Baneocin powder is, in general, applied two to four times daily, while Baneocin ointment is used two to three times daily.

In patients with burns covering more than 20% of the body surface area Baneocin powder should not be applied more often than once daily, particularly if renal function is reduced, because its active ingredients may be absorbed.

On local application neomycin doses should not exceed 1 g daily (equivalent to 200 g powder or ointment) for 7 days. For repeat courses this maximal dose should be halved.

Contraindications

Known hypersensitivity to bacitracin and/or neomycin or other aminoglycoside antibiotics.

Baneocin should not be used for extensive severe skin lesions, because drug absorption may cause ototoxicity with loss of hearing.

Baneocin has no place in patients with severe excretory disorders of cardiac or renal origin and pre-existent vestibular and/or cochlear damage, if uncontrolled absorption cannot be ruled out.

Do not use in the external auditory canal, if the tympanic membrane is perforated.

Do not apply Baneocin powder to the eyes.

Pregnancy and lactation

If Baneocin absorption cannot be ruled out, Baneocin should be used with caution in pregnant and lactating woman. Like all other aminoglycoside antibiotics, neomycin passes the placental barrier. High systemic aminoglycoside doses have been reported to cause cochlear damage in fetuses.

Side effects

If applied externally to the skin, the mucous membranes and to wound surfaces, Baneocin is generally well tolerated. Patients undergoing longterm treatment may develop allergic reactions like reddening and dryness of the skin, skin rashes and pruritus.

When used for chronic dermatoses (e. g. congestive dermatoses) or chronic otitis media, Baneocin promotes sensitization to various other drugs including neomycin. This may manifest itself in poor response to treatment.

Allergies mainly occur as contact eczema and are rare. Neomycin allergy is less common than generally assumed. It is associated with cross allergies to other aminoglycoside antibiotics in about 50% of cases.

In patients with extensive skin lesions Baneocin absorption and its consequences, e. g. vestibular and cochlear damage, nephrotoxicity and neuromuscular blockade, should be considered.

Interactions (following systemic absorption)

If systemic absorption occurs, the concomitant administration of cephalosporins and other aminoglycoside antibiotics may cause increased nephrotoxicity.

The simultaneous use of diuretics like etacrynic acid or furosemide may also aggravate signs of oto- and nephrotoxicity. In patients receiving narcotics, anesthetics or muscle relaxants neuromuscular blockade may be potentiated by Baneocin absorption.

Incompatibilities

No incompatibilities are known for bacitracin and neomycin.

Special warnings for safe use

If used in doses substantially exceeding recommended dosage levels, attention should be paid to signs of nephrotoxicity and/or ototoxicity due to potential Baneocin absorption, particularly in patients with trophic ulcers. As the risk of toxic effects is increased by reduced liver and/or kidney function, patients with hepatic and/or renal functional impairment
should undergo urine and blood tests as well as audiometry before and during intensive Baneocin treatment.

Caution should be exercised in patients with chronic otitis media of long standing because of potential ototoxicity.

Do not use in the external auditory canal, if the tympanic membrane is perforated.

If uncontrolled Baneocin absorption occurs, attention should be paid to potential neuromuscular blockade particularly in patients with acidosis, myasthenia gravis or other neuromuscular diseases. Neuromuscular blockade is antagonized by calcium or neostigmine.

On prolonged use special attention should be paid to the potential overgrowth of resistant organisms, specially fungi. In pertinent cases suitable treatment should be instituted.

In patients developing allergies and superinfections the drug should be withdrawn.

Stability

If properly stored, Baneocin powder/ointment retain their full potency to the date of expiration shown on the pack.

Storage conditions

Store below 25°C, protect from light.
Keep powder in a dry place.

Presentations

Baneocin powder:	sprinklers of 10 g
Baneocin ointment:	tubes of 20 g, single and hospital packs.

"Keep medicines out of the reach of children!"

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