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Taking corrections into account

Augmentin

Film-coated tablets

Composition

Active substances

Amoxicillin anhydrous as amoxicillin trihydrate.
Clavulanic acid as potassium clavulanate.

Excipients

Excipients per film-coated tablet.

Pharmaceutical form and active substance quantity per unit

Pharmaceutical form	Amoxicillin anhydrous as amoxicillin trihydrate	Clavulanic acid as potassium clavulanate	Ratio of amoxicillin to clavulanic acid
625 mg (500/125) film-coated tablets	500 mg	125 mg	4 : 1
1 g (875/125) film-coated tablets (with decorative groove)	875 mg	125 mg	7 : 1

Indications/Uses

Augmentin should be used in accordance with official local recommendations for antibiotics, taking into account local susceptibility data.
Augmentin is indicated for gram-positive and gram-negative bacterial infections with Augmentin-susceptible pathogens (especially bacteria that are resistant to amoxicillin due to their formation of β-lactamase, see "Properties / Effects").
ENT infections:

Tonsillitis, pharyngitis, laryngitis, otitis media, sinusitis, caused mainly by *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis and Streptococcus pyogenes.*

Lower respiratory tract infections:

Acute bronchitis with bacterial superinfection and acute exacerbation of chronic bronchitis, bacterial pneumonia, caused mainly by *Streptococcus pneumoniae, Haemophilus influenzae and Moraxella catarrhalis.*

Urinary tract infections:

Acute and chronic pyelonephritis, cystitis, urethritis, etc. caused by *Escherichia coli*.

Venereal diseases:

Gonorrhoea (specific urethritis).

Skin and soft tissue infections:

Caused mainly by *Staphylococcus aureus* and *Streptococcus pyogenes*.

Gynaecological infections:

Salpingitis, adnexitis, endometritis, bacterial vaginitis.

The susceptibility of pathogens to Augmentin may differ geographically, and can change over time. Local susceptibility data should therefore be taken into consideration and, if necessary, susceptibility tests should be performed.

Dosage/Administration

The dose depends on the age, body weight and kidney function of the patient, as well as on the severity of the infection.

Usual dosage

Adults and children over 40 kg:

For mild, moderate and severe infections, the usual posology is 3 x 625 mg (500/125) daily.
In special cases (acute sinusitis, community-acquired pneumonia, acute exacerbations of chronic bronchitis, pyelonephritis and complicated urinary tract infections), the posology is 2 x 1 g (875/125) or 3 x 625 mg (500/125) daily.
If necessary, these posologies can be doubled (up to a maximum of 3 x 1 g (875/125) daily).

Children and adolescents under 40 kg.

Augmentin film-coated tablets are not suitable for the treatment of infections in children. For the treatment of infections in children, see the Summary of Product Characteristics for Augmentin Duo/Augmentin Trio Forte Suspensions.

Special posology guidelines

Patients with impaired renal function

The excretion of amoxicillin and clavulanic acid is slowed in renal insufficiency. The Augmentin dose should therefore be as follows, depending on the degree of renal insufficiency, expressed as creatinine clearance (CrCl):

Adults and children over 40 kg:

Creatinine clearance	Mild, moderate and severe infections
10-30 ml/min	625 mg every 12 hours
less than 10 ml/min	625 mg every 24 hours

2x 1 g (875/125) should not be administered to patients with creatinine clearance below 30 ml/min.
No dose adjustment is necessary for creatinine clearances above 30 ml/min.

Haemodialysis
One additional normal dose should be given during and at the end of dialysis (as the plasma levels of amoxicillin and clavulanic acid are reduced by haemodialysis).
The 1 g film-coated tablets should only be used in patients with creatinine clearance >30 ml/min.

Elderly patients

No dose adjustment is necessary; the dose should be as in adults. In cases of renal insufficiency, the dose should be adjusted as for adults with renal insufficiency.

Method of administration

Augmentin should be taken at the start of a meal, with at least half a glass of water. This will optimise absorption and gastrointestinal tolerance.
Parenteral therapies may be continued orally.
The fracture score on the 1 g film-coated tablet is only intended to make it easier to take the tablet.
The film-coated tablets are not intended for halving the dosage.

Contraindications

Augmentin is contraindicated in patients with known hypersensitivity to penicillins and cephalosporins, or to any of the ingredients of Augmentin, as well as in patients who developed jaundice or hepatic impairment during a previous Augmentin therapy.
Infectious mononucleosis, lymphatic leukaemia: when treated with amoxicillin, patients with these conditions are especially predisposed to skin rashes.

Warnings and precautions

Before initiating therapy with Augmentin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, clavulanic acid, cephalosporins or other allergens.
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients treated with penicillins. Hypersensitivity reactions can also lead to Kounis syndrome, a severe allergic reaction that can lead to a myocardial infarction. The first symptoms of such reactions may include chest pain associated with an allergic reaction to amoxicillin-clavulanate (see "Adverse reactions").
If an allergic reaction occurs, Augmentin should be discontinued and other appropriate therapies initiated. Preparations should be made for emergency measures in the event of anaphylactic or anaphylactoid reactions. Such reactions call for the immediate injection of adrenaline (caution: cardiac arrhythmias). If necessary, the adrenaline may be repeated. Thereafter, IV glucocorticoids should be given (e.g. 250–1000 mg prednisolone). The glucocorticoid injection can be repeated if necessary. Oxygen, intravenous steroids and mechanical ventilation, with intubation, may also be required. (In children, the posology of the preparations must be adapted to their body weight and age.) Further therapeutic measures such as the intravenous injection of antihistamines and volume expanders should be considered. Careful monitoring of the patient is required as symptoms could reoccur.
Severe cutaneous drug reactions (SCAR) such as Stevens-Johnson syndrome, toxic epidermal necrolysis, drug-related exanthema with eosinophilia and systemic symptoms (DRESS), erythema multiforme and acute generalised exanthematous pustulosis (AGEP) have been reported in patients treated with beta-lactam antibiotics, including amoxicillin trihydrate potassium clavulanate (see also "Undesirable effects"). If such reactions occur, Augmentin should be discontinued immediately and alternative therapy should be considered.
Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children who have received amoxicillin/clavulanic acid (see "Undesirable effects"). DIES is an allergic reaction with the main symptom of persistent vomiting (1–4 hours after taking the drug) without the presence of allergic skin or respiratory symptoms. Other symptoms may include abdominal pain, lethargy, diarrhoea, hypotension or leukocytosis with neutrophilia. Severe cases have occurred, including progression to shock.
If such reactions occur, Augmentin should be discontinued immediately and alternative therapy should be considered.
In cases of limited kidney function, the time between administrations should be increased based on the severity of the impairment (see "Special dosage instructions").
Long-term use can lead to the proliferation of non-susceptible bacteria. Such cases must be diagnosed appropriately and suitable treatment must be initiated.
The appearance of diarrhoea during or after treatment with Augmentin, especially when severe, persistent and/or bloody, could be a symptom of an infection with Clostridium difficile. The most severe form of such infections is pseudomembranous colitis. If this complication is suspected, the

Augmentin treatment must be discontinued immediately and the patient must be examined thoroughly in order to initiate specific antibiotic therapy (e.g., metronidazole, vancomycin) as needed. The use of peristalsis inhibitors is contraindicated in these clinical situations.
During long-term therapy, kidney, liver and haematopoietic function should be verified regularly.
There have been rare reports of abnormal prolongation of prothrombin time (increased INR) in patients receiving amoxicillin/clavulanic acid and oral anticoagulants. Therefore, appropriate monitoring should be carried out whenever concomitant anticoagulants are prescribed. In order to maintain the desired level of anticoagulation, the dose of the oral anticoagulants may need to be adjusted.
Augmentin should be used with caution in cases of hepatic impairment.
In severe gastrointestinal disturbances, with vomiting and diarrhoea, adequate absorption of Augmentin is no longer guaranteed. Parenteral use should be considered in such cases.
In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. A possible consequence of the formation of crystals is acute kidney failure. When high doses of amoxicillin are administered, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria. At high concentrations in the urine, amoxicillin can precipitate at room temperature in the bladder catheter. Therefore, normal urine flow in the catheter should be monitored regularly.
Because oral antibiotics could reduce the efficacy of oral contraceptives, patients should be advised to take additional contraceptive measures during treatment with Augmentin.

Interactions

Probenecid inhibits renal tubular elimination of amoxicillin, but not of clavulanic acid. Concomitant use with Augmentin may result in increased and prolonged blood levels of amoxicillin. Concomitant use is not recommended.
Oral contraceptives: During treatment with amoxicillin, the enterohepatic circulation of oral contraceptives may be reduced or completely eliminated due to impairment of the intestinal flora. The efficacy of contraceptives is reduced as a result.
Because amoxicillin only acts on bacteria during their growth phase, there is an interaction with bacteriostatic antibiotics.
There is a possible interaction with glycosides (e.g. digoxin), as glycoside absorption is increased in certain patients due to damage to the intestinal flora during treatment with antibiotics.
Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no available data on the combination of Augmentin with allopurinol.
Rare cases of an increased International Normalised Ratio (INR) have been reported in the literature in patients treated with acenocoumarol or warfarin in whom amoxicillin was prescribed. If concomitant administration is necessary, the prothrombin time or International Normalised Ratio should be monitored carefully when amoxicillin is added or discontinued.

In patients receiving mycophenolate mofetil, reduction by approximately 50% in the pre-dose concentration of the active metabolite mycophenolic acid (MPA) has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose levels may not accurately represent changes in overall MPA exposure.
Penicillins can reduce the excretion of methotrexate, which can lead to a potential increase in toxicity.

Pregnancy/Lactation

Pregnancy

Reproduction studies in animals (mice and rats, with doses up to 10 times higher than in humans) with Augmentin administered orally and parenterally showed no teratogenic effects.
In a study in women with premature rupture of the foetal membrane, prophylactic treatment with Augmentin was reported to be associated with an elevated risk of necrotising enterocolitis in neonates (1.5% incidence of proven necrotising enterocolitis in neonates with Augmentin treatment versus 0.5% without Augmentin treatment).
During pregnancy, Augmentin should therefore not be used unless clearly necessary.

Breastfeeding

Traces of Augmentin pass into breast milk and therefore hypersensitivity reactions may occur in sensitive neonates. Though impairment of the intestinal flora of infants is theoretically possible, it has not been found at the recommended doses.
Breastfeeding is therefore not recommended during treatment with Augmentin.

Effects on ability to drive and use machines

Certain drug reactions that vary depending on the individual (see "Undesirable effects") may affect the concentration and reaction in the patient to an extent that impairs the ability to drive and use machines.

Undesirable effects

The frequencies from very common to rare undesirable effects come from datasets in major clinical trials. The frequencies of the remaining adverse reactions (i.e. with incidence < 1/10,000) derive mainly from data during use (post-marketing reports) and therefore relate to the reporting frequency and not the actual number of occurrences.
The frequencies of the undesirable effects are classified as follows: Very common (≥1/10), common (<1/10 to ≥1/100), uncommon (<1/100 to ≥1/1,000), rare (<1/1,000 to ≥1/10,000), very rare (<1/10,000), unknown (frequency cannot be estimated on the basis of the available data).

Infections and infestations

Common: Mucocutaneous candidiasis.

Diseases of the blood and lymphatic system

Rare: Reversible leukopenia (including severe neutropenia) and thrombocytopenia.

Very rare: Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding time and prothrombin time (Quick value) (see "Warnings and precautions" and "Interactions").

Data during use (Post-Marketing Data)

Rare: Thrombocytosis.

Immune system disorders

Very rare: Angioneurotic oedema, anaphylactic reaction, serum sickness-like syndrome, hypersensitivity vasculitis (see "Skin and subcutaneous tissue disorders"). Anaphylactic shock requires the immediate injection of adrenaline (see "Warnings and precautions").

Data from clinical studies

Common: Reversible eosinophilia (hypersensitivity reaction).

Data during use (Post-Marketing Data)

Very rare: Anaphylactic reactions (with symptoms such as urticaria, pruritic erythema, angioneurotic oedema, abdominal pain, vomiting among other abdominal symptoms, dyspnoea in bronchospasm or laryngeal oedema, circulatory symptoms such as hypotension and even anaphylactic shock). A Herxheimer reaction may occur during therapy for typhus, syphilis or leptospirosis. The treatment must be immediately discontinued if a hypersensitivity reaction occurs (see "Skin and subcutaneous tissue disorders").

Nervous system disorders

Uncommon: Dizziness, headache.

Very rare: Reversible hyperactivity, clonic convulsions. Clonic convulsions may occur in patients with impaired kidney function or in patients receiving high doses.

Frequency unknown: Aseptic meningitis

Data during use (Post-Marketing Data)

Very rare: Agitation, anxiety, insomnia, confusion, behavioural changes, dizziness, dysaesthesia.

Cardiac disorders

Data during use (Post-Marketing Data)

Frequency unknown: Kounis syndrome (see "Warnings and precautions").

Gastrointestinal disorders

Very common: Diarrhoea.

Common: Nausea, vomiting.

Nausea is more commonly observed at higher oral doses. If gastrointestinal reactions occur, they can be reduced by taking Augmentin at the start of a meal.

Uncommon: Dyspepsia, loss of appetite, stomach pressure, flatulence.

Rare: Glossitis, stomatitis.

Very rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) (see "Warnings and precautions").

There have been reports of superficial tooth discolouration in children, especially following use of the suspension. Good oral hygiene could prevent the occurrence of tooth discolouration, as it can generally be removed by brushing.

Black hairy tongue (only after use of the oral forms).

A cohort study of 576 nine-year-old children showed that the administration of amoxicillin between the ages of 0 and 9 months significantly increases the risk of fluorosis of the definitive maxillary incisors. The fluorosis may present as white streaks, cosmetically disturbing discolouration, dents in the enamel and even tooth deformation.

Frequency unknown: Acute pancreatitis (see "Warnings and precautions"), drug-induced enterocolitis syndrome *(DIES)* (post-marketing data).

Data from clinical studies

Very common: Loose stools.

Common: Stomach pain.

Liver and bile diseases

Uncommon: A moderate rise in AST and/or ALT levels has been noted in patients receiving Augmentin.

Transient increase of lactate dehydrogenase and alkaline phosphatase levels.

Rare: Hepatitis and cholestatic icterus.

The risk appears to be slightly higher with prolonged treatment, age ≥65 years and in men. Reports of such adverse effects are extremely rare in children. The incidence of these adverse effects with Augmentin is approximately 5 times greater than with amoxicillin alone.

The signs and symptoms usually occur during or shortly after treatment, and can also be observed up to several weeks after the end of treatment in individual cases. They are usually reversible. Liver disorders can be severe and even fatal in extremely rare situations. However, these cases occurred almost exclusively in patients with a serious underlying disease or using concomitant medicinal products known to have potential adverse effects on the liver.

Skin and subcutaneous tissue disorders

Uncommon: Skin rash (in the form of maculo-papular or morbilliform rashes) and erythema, pruritus, urticaria.

Rare: Erythema multiforme.

Very rare: Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) and drug-related exanthema with eosinophilia and systemic symptoms (DRESS) (see "Immune system disorders").
If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued (see also "Warnings and precautions").
Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome)

Frequency unknown: Linear Ig A disease.

Renal and urinary disorders

Very rare: Interstitial nephritis,
Renal impairment with increased BUN and serum creatinine concentration.

Frequency unknown: Crystalluria (including acute renal damage)

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

In case of overdose, gastrointestinal symptoms and fluid and electrolyte balance disturbances may occur. These can be treated symptomatically with activated charcoal and hydration.
Augmentin can be removed from the body by haemodialysis.
Large overdoses of amoxicillin, especially when administered parenterally, lead to very high urine levels.
Amoxicillin crystalluria and accompanying acute kidney failure have been observed (see "Warnings and precautions").

Properties/Effects

ATC code

J01CR02

Mechanism of action

Augmentin is a bactericidal antibiotic. Amoxicillin is a semisynthetic aminopenicillin in the group of β-lactam antibiotics and has bactericidal activity against gram-positive and gram-negative bacteria. The bactericidal effect of amoxicillin relies on the inhibition of bacterial cell wall synthesis by blocking the transpeptidase. Amoxicillin is stable in the presence of acid, but is sensitive to penicillinases.
Clavulanic acid is a β-lactam, which has a mild antibacterial effect against some bacteria strains. The principal action of clavulanic acid is its enzyme-inhibiting activity against many types of β-lactamases. Clavulanic acid has high activity against clinically relevant plasmid-mediated β-lactamases that are often responsible for transmitted antibiotic resistance, but is generally less effective against chromosomally mediated type 1 β-lactamases.
This inhibition protects amoxicillin from destruction by β-lactamases, thereby allowing amoxicillin to mediate its full antibiotic effect.
Many bacteria that are resistant to amoxicillin because they produce β-lactamase are susceptible to this combination of amoxicillin and clavulanic acid. This synergistic effect is achieved at clavulanic acid concentrations reached in the body following parenteral or oral administration.

Pharmacodynamics

Scope of action
In vitro susceptibility of pathogens
The following list classifies the bacteria by their *in-vitro* susceptibility to Augmentin.

* Clinical efficacy of Augmentin has been demonstrated in clinical studies.
+ Bacteria that do not produce β-lactamases. If an isolate is susceptible to amoxicillin, it can be considered as susceptible to Augmentin.

Commonly susceptible bacteria:
Gram-positive aerobes:

- Bacillus anthracis
- Enterococcus faecalis
- Listeria monocytogenes
- Nocardia asteroides
- Streptococcus pneumoniae*+
- Streptococcus pyogenes*+

- Streptococcus agalactiae*+
- Streptococcus viridans+
- Streptococcus spp. (other β-haemolytic streptococci)*+
- Staphylococcus aureus (methicillin-susceptible)*
- Staphylococcus saprophyticus (methicillin-susceptible)
- Coagulase-negative staphylococcus (methicillin susceptible)

Gram-negative aerobes:

- Bordetella pertussis
- Haemophilus influenzae*
- Haemophilus parainfluenzae
- Helicobacter pylori
- Moraxella catarrhalis*
- Neisseria gonorrhoeae
- Pasteurella multocida
- Vibrio cholerae

Other:

- Borrelia burgdorferi
- Leptospira icterohaemorrhagiae
- Treponema pallidum

Gram-positive anaerobes:

- Clostridium spp.
- Peptococcus niger
- Peptostreptococcus magnus
- Peptostreptococcus micros
- Peptostreptococcus spp.

Gram-negative anaerobes:

- Bacteroides fragilis
- Bacteroides spp.
- Capnocytophaga spp.
- Eikenella corrodens
- Fusobacterium nucleatum
- Fusobacterium spp.
- Porphyromonas spp.
- Prevotella spp.

Bacteria for which acquired resistance may be a problem:

Gram-negative aerobes:

- Escherichia coli*
- Klebsiella oxytoca
- Klebsiella pneumoniae*
- Klebsiella spp.
- Proteus mirabilis
- Proteus vulgaris
- Proteus spp.
- Salmonella spp.
- Shigella spp.

Gram-positive aerobes:

- Corynebacterium spp.
- Enterococcus faecium

Inherently resistant bacteria:

Gram-negative aerobes:

- Acinetobacter spp.
- Citrobacter freundii
- Enterobacter spp.
- Hafnia alvei
- Legionella pneumophila
- Morganella morganii
- Providencia spp.
- Pseudomonas spp.
- Serratia spp.
- Stenotrophomonas maltophilia
- Yersinia enterocolitica

Other:

- Chlamydia pneumoniae
- Chlamydia psittaci
- Chlamydia spp.
- Coxiella burnetti
- Mycoplasma spp.

Clinical efficacy

No information.

Pharmacokinetics

Absorption

Amoxicillin and clavulanic acid are readily absorbed in the intestines. Absorption is optimised when taken at the start of a meal. The absorption curves of both components are similar. The maximum serum levels of amoxicillin and clavulanic acid are reached within approximately 1 to 1½ hours following oral intake. After taking one 375 mg tablet (250/125), the serum levels are about 5 mg/l (amoxicillin) and 3 mg/l (clavulanic acid).
The total quantities absorbed are generally 80% for amoxicillin and 70% for clavulanic acid.

Distribution

About 18% of amoxicillin and 25% of clavulanic acid are bound to plasma proteins. The volume of distribution is 22 litres for amoxicillin and 16 litres for clavulanic acid.
Because high serum levels of amoxicillin and clavulanic acid are reached following oral administration of Augmentin, good penetration into bodily fluids can be expected.
Therapeutic concentrations of both active substances have been found in abdominal tissue, the gall bladder, skin, fat and muscle tissues and in the following bodily fluids: synovial, peritoneal and pleural fluids, bile, sputum and pus.
Both active substances cross the placental barrier. Reproduction studies in animals did not find harmful effects. Clinical experience in humans is limited.
Small quantities of amoxicillin are found in breast milk. Only trace quantities of clavulanic acid are detected in breast milk. With the exception of the risk of a hypersensitivity reaction associated with this type of excretion, no adverse effects are known in the infant.

Metabolism

Up to 10-25% of amoxicillin is metabolised into the corresponding inactive form penicilloic acid and excreted via the kidneys. Up to 35-60% of clavulanic acid is converted into inactive metabolites.

Elimination

Amoxicillin and clavulanic acid are chiefly eliminated via the kidneys. Approximately 60 to 70% of the amoxicillin and approximately 40 to 65% of the clavulanic acid are excreted unchanged in active form in the urine within the first 6 h after oral administration.
The elimination half-life of amoxicillin and clavulanic acid is approximately 1–1½ hours in subjects with normal kidney function.

Kinetics in special patient groups

Renal impairment

In renal insufficiency, the renal elimination of both active substances is delayed, and therefore the dose must be adjusted accordingly. The plasma levels of both active substances are greatly reduced by haemodialysis.

Preclinical data

Administration of the combination of amoxicillin and clavulanate (2:1) or of clavulanate alone was not found to have an effect in the F0 generation of rats or mice with regard to mating behaviour, fertility, gestation (including embryonic and foetal development) or birthing. Furthermore, studies have not revealed any adverse effects on embryo-foetal development or negative effects on the viability, growth, development, behaviour or reproductive function of the F1 progeny.
Potassium clavulanate was detected when tested alone and in combination with amoxicillin (1:2 or 1:4) in a wide range of genotoxicity tests under *in-vitro* and *in-vivo* conditions, with very different endpoints. The results obtained lead to the conclusion that the administration of amoxicillin or clavulanate poses no genotoxic dangers.

Other information

Incompatibilities

None known.

Influence on diagnostic methods

Possible falsification of results of oestriol tests in pregnant women.
The high concentration of amoxicillin in the urine can affect (false-positive results) glucose tests by chemical methods (Benedict's or Fehling's solution as well as Clinitest). Therefore, glucose tests should be performed by enzymatic (glucose oxidase) methods (Dextrostix, Diastix or Clinistix).
The direct Coombs test can come back positive, though haemolysis has not occurred.
In the amino acid chromatography of urine, amoxicillin or its degradation products could give ninhydrin-positive spots.
Possible interference with urine and serum total protein tests by a colour reaction (Ehrlich's ninhydrin reaction).
Possible false-positive colour reaction in glycosuria tests.
Falsely elevated serum uric acid levels can occur when the copper-chelating method is used. The Wolfram phosphate and uricase methods for uric acid are not affected by amoxicillin.

Shelf life

Do not use this medicine after the expiry date which is stated on the pack after "EXP".

Special precautions for storage

Store in a dry place in the original package, at room temperature (15–25 °C). Keep out of the reach of children.

Marketing authorisation number

625 mg film-coated tablets: 45,674 (Swissmedic)
1 g film-coated tablets: 53,692 (Swissmedic)

Packs

Augmentin 625 mg (500/125) film-coated tablets: Pack of 20 film-coated tablets **(A).**
Augmentin 1 g (875/125) film-coated tablets (with decorative groove): Packs of 12 and 20 film-coated tablets **(A).**

Marketing authorisation holder

GlaxoSmithKline AG, 3053 Münchenbuchsee

Date of revision of the text

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