

## **Augmentin clavulanate-potentiated amoxycillin.**

### **Contributors**

Beecham Research Laboratories

### **Publication/Creation**

Brentford, Middlesex : Beecham Research Laboratories, 1981.

### **Persistent URL**

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Wellcome Collection  
183 Euston Road  
London NW1 2BE UK  
T +44 (0)20 7611 8722  
E [library@wellcomecollection.org](mailto:library@wellcomecollection.org)  
<https://wellcomecollection.org>

# AUGMENTIN

clavulanate-potentiated amoxycillin

## Prescribing Information

### PRESENTATION

▼ **AUGMENTIN TABLETS:** white oval film coated tablets engraved 'AUGMENTIN' on one side. Each tablet contains potassium clavulanate equivalent to 125 mg clavulanic acid with amoxycillin trihydrate equivalent to 250 mg amoxycillin.

▼ **AUGMENTIN DISPERSIBLE TABLETS:** white round tablets engraved 'AUGMENTIN'. Each tablet contains potassium clavulanate equivalent to 125 mg clavulanic acid with amoxycillin trihydrate equivalent to 250 mg amoxycillin.

### USES

AUGMENTIN is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The novel action of clavulanate extends the spectrum of amoxycillin to embrace a wider range of organisms, including many resistant to other  $\beta$ -lactam antibiotics. AUGMENTIN is indicated for the short term oral treatment of common bacterial infections such as:  
**Upper Respiratory Tract Infections (including ENT)**  
e.g. tonsillitis sinusitis otitis media

**Lower Respiratory Tract Infections**  
e.g. acute and chronic bronchitis  
lobar and bronchopneumonia

**Genito-urinary Tract Infections**  
e.g. cystitis urethritis pyelonephritis  
septic abortion puerperal sepsis

**Other infections**  
e.g. skin and soft tissue infections  
intra-abdominal sepsis osteomyelitis

AUGMENTIN is bactericidal to a wide range of organisms including:

### GRAM-POSITIVE

**Aerobes**  
Streptococcus faecalis  
Streptococcus pneumoniae  
Streptococcus pyogenes  
Streptococcus viridans  
Staphylococcus aureus  
Corynebacterium species  
Bacillus anthracis  
Listeria monocytogenes

**Anaerobes**  
Clostridium species  
Peptococcus species  
Peptostreptococcus

### GRAM-NEGATIVE

**Aerobes**  
Haemophilus influenzae  
Escherichia coli  
Proteus mirabilis  
Proteus vulgaris  
Klebsiella species  
Salmonella species  
Shigella species  
Bordetella pertussis  
Brucella species  
Neisseria gonorrhoeae  
Neisseria meningitidis  
Vibrio cholerae  
Pasteurella septica

**Anaerobes** Bacteroides species

### DOSAGE AND ADMINISTRATION

#### Dosage

#### Adults and Children over 12 years

1 AUGMENTIN or AUGMENTIN DISPERSIBLE tablet (375 mg) three times a day. In severe infections this may be increased to two tablets three times a day. Treatment with AUGMENTIN should not be extended beyond 14 days without review.

At present there is insufficient clinical evidence to permit a firm dosage recommendation to be made for younger children.

#### Administration

The absorption of AUGMENTIN is unaffected by food. Dispersible tablets should be stirred into a little water before taking.

### CONTRA-INDICATIONS, WARNINGS etc.

**Contra-indication:** Penicillin hypersensitivity

**Precautions:** A number of studies at high dosages have shown AUGMENTIN to be free from teratogenicity in animals; however, its safety in human pregnancy has not yet been established.

Renal impairment delays the excretion of clavulanate and amoxycillin but unless impairment is severe enough to require dialysis, no reduction of dosage is necessary. Each 375mg tablet contains 0.63mmol of potassium.

**Side-Effects:** Side-effects, as with amoxycillin, are uncommon and mainly of a mild and transitory nature. Diarrhoea, indigestion, nausea, vomiting and candidiasis

Continued overleaf

have been reported. Nausea, although uncommon, is more often associated with higher dosages. If gastrointestinal side-effects occur they may be reduced by taking AUGMENTIN at the start of meals. Urticarial and erythematous rashes sometimes occur but their incidence has been particularly low in clinical trials. Erythematous rashes have been associated with glandular fever in a few patients receiving amoxycillin. Treatment should be discontinued if either type of rash appears.

#### PHARMACEUTICAL PRECAUTIONS

AUGMENTIN preparations should be stored in a dry place. Bottles of AUGMENTIN tablets should be kept tightly closed and the tablets should be dispensed in moisture-proof containers.

#### LEGAL CATEGORY

POM

#### PACKAGE QUANTITIES AND PRICES

AUGMENTIN TABLETS: Bottles of 30 (7.50)  
and 100 (£25.00)

AUGMENTIN DISPERSIBLE TABLETS: Foil wrapped in cartons of  
30 (£8.43) and 90 (£25.30).

Prices correct at date of printing.

#### FURTHER INFORMATION

AUGMENTIN is a novel concept in antibiotic therapy. Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in AUGMENTIN anticipates this defence mechanism by blocking the  $\beta$ -lactamase enzymes, thus rendering the organisms sensitive to amoxycillin's rapid bactericidal effect at concentrations readily attainable in the body. Clavulanate by itself has little antibacterial activity; however, in association with amoxycillin as AUGMENTIN it produces a novel antibiotic agent of broad spectrum with wide application in hospital and general practice. The pharmacokinetics of the two components of AUGMENTIN are closely matched. Peak serum levels of both occur about 1 hour after oral administration. Both clavulanate and amoxycillin have low levels of serum binding; about 70% remains free in the serum. Doubling the dosage of AUGMENTIN approximately doubles the serum levels achieved.

#### PRODUCT LICENCE NUMBERS

AUGMENTIN TABLETS	PL 0038/0270
AUGMENTIN DISPERSIBLE TABLETS	PL 0038/0272

Date of printing

September 1981



Sold and Supplied by:

## Beecham Research Laboratories

Great West Road Brentford Middlesex TW8 9BD

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Our Medical Department is always available for advice on clinical problems. Enquiries should be addressed to:

Medical Department  
Beecham Research Laboratories  
Freepost  
Brentford  
Middlesex TW8 9BD