AUGMENTIN IV 0,6 & 1,2

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

AUGMENTIN IV 0,6 Powder for injection

AUGMENTIN IV 1,2 Powder for injection

COMPOSITION:

AUGMENTIN IV 0,6: powder for intravenous injection containing amoxicillin sodium equivalent to 500 mg of amoxicillin and potassium clavulanate equivalent to 100 mg clavulanic acid.

AUGMENTIN IV 1,2: powder for intravenous injection containing amoxicillin sodium equivalent to 1 000 mg of amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid.

AUGMENTIN IV contains no other ingredients.

Sugar-free.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Bactericidal action - The amoxicillin component of the formulations exert a bactericidal action against many strains of Gram-positive and Gram-negative organisms. The clavulanic acid component has very little bactericidal action. It does however, by inactivation of susceptible beta-lactamases, protect amoxicillin from degradation by a

large number of beta-lactamase enzymes produced by penicillin resistant strains of organisms. Potassium clavulanate has been shown *in vitro* to be an irreversible inhibitor of beta-lactamases.

Pharmacokinetic properties:

Absorption:

The pharmacokinetics of amoxicillin and clavulanic acid are closely allied. Doubling the dose virtually doubles the peak serum level.

Excretion:

Co-administration of probenecid has little effect on the excretion of the clavulanic acid component of the formulation.

INDICATIONS:

AUGMENTIN IV is indicated for the treatment of infections caused by amoxicillin resistant organisms producing β-lactamases sensitive to clavulanic acid:

- upper respiratory tract infections, such as sinusitis, otitis media, tonsillitis caused by *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis* and *Streptococcus pyogenes* sensitive to AUGMENTIN IV
- lower respiratory tract infections, such as bronchitis (caused by amoxicillin-resistant β-lactamase producing *Escherichia coli*, *Haemophilus influenzae* and *Haemophilus para-influenzae*), bronchopneumonia sensitive to AUGMENTIN IV
- urinary tract infections, such as cystitis, urethritis, pyelonephritis caused by *Enterobacteriaceae (*mainly *Escherichia coli), Staphylococcus saprophyticus* and *Enterococcus* species
- skin and soft tissue infections caused by methicillin susceptible *Staphylococcus aureus, Streptococcus pyogenes* and *Bacteroides* species sensitive to AUGMENTIN IV.

AUGMENTIN IV will also be effective in the treatment of infections caused by amoxicillin-sensitive organisms at the appropriate amoxicillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

CONTRA-INDICATIONS:

Hypersensitivity to penicillins, amoxicillin and cephalosporins or any other ingredient of AUGMENTIN.

Safety and efficacy in children has not been established with the parenteral forms of AUGMENTIN.

AUGMENTIN is contra-indicated in patients with a previous history of AUGMENTIN-associated jaundice/hepatic dysfunction.

WARNINGS AND SPECIAL PRECAUTIONS:

Serious and occasionally fatal hypersensitivity reactions including anaphylaxis have been reported in patients on therapy with a penicillin. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with AUGMENTIN, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, AUGMENTIN IV should be discontinued and the appropriate therapy instituted which may include epinephrine (adrenaline), corticosteroids and antihistamines.

Since AUGMENTIN contains amoxicillin, an aminopenicillin, it is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is

a high incidence of morbilliform rash if amoxicillin is used. AUGMENTIN should be avoided if infectious mononucleosis is suspected**.**

Prolonged use may also result in overgrowth of non-susceptible organisms. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Aerobacter*, *Pseudomonas* or *Candida*), the agent should be discontinued and/or appropriate therapy instituted.

Abnormal prolongation of prothrombin time (increased international normalised ratio (INR)) has been reported in patients receiving amoxicillin-clavulanate and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Changes in liver function tests have been observed in some patients receiving AUGMENTIN. Transient hepatitis and cholestatic jaundice has been reported. AUGMENTIN should be used with caution in patients with evidence of hepatic dysfunction.

In patients with moderate or severe renal impairment AUGMENTIN dosage should be adjusted according to the degree of renal impairment (see DOSAGE AND DIRECTIONS FOR USE).

The presence of clavulanic acid in amoxicillin-clavulanate may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

If the parenteral administration of high doses is necessary, the sodium content must be taken into account in patients on a sodium restricted diet. In patients with reduced urine output, crystalluria has been observed with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria (refer to KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT).

AUGMENTIN IV should **not** be given intramuscularly or subcutaneously.

AUGMENTIN IV should **not** be mixed with aminoglycosides in the same syringe or giving set, as substantial inactivation of the aminoglycosides can result.

AUGMENTIN IV should be used with caution in patients with a history of gastro-intestinal disease, especially antibiotic associated colitis since penicillins may cause pseudomembranous colitis.

Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy.

AUGMENTIN should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to amoxicillin induced skin rashes.

INTERACTIONS:

Probenecid decreases the renal tubular secretion of amoxicillin, but does not affect clavulanic acid excretion. Concomitant use with AUGMENTIN may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

The concomitant administration of allopurinol and ampicillin substantially increases the incidence of rashes in patients receiving both agents as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients. There is no data on AUGMENTIN and allopurinol administered concomitantly.

No information is available about the concurrent use of AUGMENTIN and alcohol. However, the ingestion of alcohol whilst being treated with some other beta-lactam antibiotics has precipitated a disulfiram-like reaction in some patients. Therefore, the ingestion of alcohol should be avoided during and for several days after treatment with AUGMENTIN.

Following administration of ampicillin to pregnant woman a transient decrease in plasma concentration of total conjugate oestriol, oestriol-glucuronide, conjugated oestrone and oestradiol has been noted. This effect may also occur with AUGMENTIN leading to lower oestrogen re-absorption and reduced efficacy of combined oral contraceptives.

The use of AUGMENTIN may lead to the selection of resistant strains of organisms and sensitivity testing should, therefore, be carried out whenever possible, to demonstrate the appropriateness of therapy.

Intravenous administration can cause local irritation, induration and phlebitis at the injection site.

The presence of clavulanic acid in amoxicillin-clavulanate may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test (antiglobulin test).

Increased INR ratio in patients maintained on warfarin and prescribed a course of AUGMENTIN may occur. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of AUGMENTIN.

PREGNANCY AND LACTATION:

Use in pregnancy:

Safety in pregnancy has not been established**.**

In women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates.

Use in lactation:

Amoxicillin is excreted in the milk. There is no data on the excretion of clavulanic acid in human milk. Mothers on treatment with AUGMENTIN should not breastfeed their infants.

DOSAGE AND DIRECTIONS FOR USE:

Directions for use:

AUGMENTIN IV 0,6 powder for injection can be reconstituted by dissolving in 10 ml Water for Injections B.P.

AUGMENTIN IV 1,2 powder for injection can be reconstituted by dissolving in 20 ml Water for Injections B.P.

When a diluent is added a transient pink colouration or slight opalescence will be observed whereafter, a pale yellow fluid.

For intravenous infusion, the reconstituted vial should be further diluted with the desired volume of a suitable infusion fluid (see Compatibility and stability below).

Compatibility and stability:

The period of stability of AUGMENTIN IV infusion fluids after reconstitution and dilution are as follows:

STRENGTH	INFUSION FLUID	VOLUME OF FLUID INFUSION (ml)		STABILITY (hours)	
		AUGMENTIN IV 0,6	AUGMENTIN IV 1,2	*5 °C	25 °C
AUGMENTIN IV 0,6 600 mg reconstituted with 10 ml Water for Injections	Water for Injections	50	100	8	4
	Sodium Chloride Intravenous Infusion B.P. (0,9 % *m/v*)	50	100	8	4
	Compound Sodium Lactate Intravenous Infusion (M/6)	50	100		4
AUGMENTIN IV 1,2 1,2 g reconstituted with 20 ml Water for Injections	Compound Sodium Chloride Injection (Ringer's Solution)	50	100		3
	Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution; Ringer-Lactate Solution)	50	100		3
	Potassium Chloride and Sodium Chloride Intravenous Infusion B.P.	50	100		3

*For storage at 5 °C, the reconstituted solutions should be added to a pre-refrigerated bag of infusion fluid. In use, the solution should be allowed to reach room temperature and then administered without delay.

For MINI-BAG™ PLUS:

Alternatively, if minibags of sodium chloride 0,9 % *m/v* are to be used, the stability results obtained with AUGMENTIN indicated that 600 mg per 50 ml or 1,2 g per 100 ml bag is suitable. Using a MINI-BAG™ PLUS unit containing 50 ml or 100 ml physiological saline,

the appropriate volume of sodium chloride solution may be transferred from the MINI-BAG™ PLUS unit bag into an AUGMENTIN IV 0,6 or AUGMENTIN IV 1,2 vial respectively, and then back into the bag after dissolution. When the latter method is used the permissible time between preparation of the solution and completion of the infusion is reduced from 4 hours to 3 hours.

AUGMENTIN IV vials should **not** be reconstituted or mixed with:

- dextrose solution
- sodium bicarbonate solution for injection
- protein hydrolysates or other proteinaceous fluids
- blood or plasma
- intravenous lipids.

However, the reconstituted solution may be injected into the drip tubing of infusion fluids containing glucose, bicarbonate and dextran over a period of 3-4 minutes.

Administration:

Note: AUGMENTIN IV vials are not suitable for intramuscular or subcutaneous administration.

The reconstituted vials can be administered intravenously by injection (2 minutes) or slow intravenous infusion (30 minutes). Infusion should be completed within the period of stability of AUGMENTIN IV infusions after reconstitution and dilution as reflected in the table under the section “Compatibility and stability” presented above. The contents of the vials must be used within 20 minutes and thereafter any unused material discarded.

Dosages:

General Information:

For infections caused by amoxicillin sensitive organisms the dosage is that approved for amoxicillin as the clavulanic acid component does not contribute to the therapeutic effect.

Adult (intravenous):

For severe infections of the respiratory tract, urinary tract and skin and soft tissue requiring parenteral therapy initially 1 AUGMENTIN IV 1,2 vial containing the equivalent of 1 000 mg amoxicillin and 200 mg clavulanic acid, can be administered intravenously 6 to 8 hourly by intravenous injection (2 minutes) or intravenous infusion (30 minutes) until condition settles followed by oral therapy with AUGMENTIN tablets at the recommended dose. If no response has occurred within 48 hours therapy must be reviewed.

Intravenous treatment with AUGMENTIN should not be extended beyond 10 days without review and the total daily administration of clavulanic acid should not exceed 800 mg. Treatment can be continued with AUGMENTIN tablets orally where appropriate after a satisfactory therapeutic response has been obtained.

Dosage Guide:

AMOXICILLIN-SENSITIVE ORGANISMS

PRODUCT	**UPPER RESPIRATORY TRACT INFECTIONS**	**LOWER RESPIRATORY TRACT INFECTIONS**	**URINARY TRACT INFECTIONS**	**SKIN & SOFT TISSUE INFECTIONS**
ADULTS:				
AUGMENTIN IV 1,2	1 vial [1)] 6-8 hourly	1 vial [1)] 6-8 hourly	1 vial [1)] 6-8 hourly	1 vial [1)] 6-8 hourly
AUGMENTIN IV 0,6	2 vials [1)] 6-8 hourly	2 vials [1)] 6-8 hourly	2 vials [1)] 6-8 hourly	2 vials [1)] 6-8 hourly

AMOXICILLIN RESISTANT ORGANISMS

PRODUCT	UPPER RESPIRATORY TRACT INFECTIONS (otitis media) *H. influenzae* *H. para influenzae*	LOWER RESPIRATORY TRACT INFECTIONS (bronchitis) *H. influenzae* *H. para influenzae*	URINARY TRACT INFECTIONS *E. coli* *Klebsiella pneumoniae*	SKIN & SOFT TISSUE INFECTIONS *Staphylococcus aureus*
ADULTS:				
AUGMENTIN IV 1,2	1 vial [1)] 6-8 hourly	1 vial [1)] 6-8 hourly	1 vial [1)] 6-8 hourly	1 vial [1)] 6-8 hourly
AUGMENTIN IV 0,6	2 vials [1)] 6-8 hourly	2 vials [1)] 6-8 hourly	2 vials [1)] 6-8 hourly	2 vials [1)] 6-8 hourly

1) Intravenous therapy should not be continued for longer than 10 days.

NOTE:

1. Insufficient evidence exists at present to recommend an intravenous dosage in children.
2. **Patients with renal impairment:**
   - Each AUGMENTIN IV 0,6 vial contains 0,5 mmol of potassium and 1,4 mmol of sodium.
   - Each AUGMENTIN IV 1,2 vial contains 1,0 mmol of potassium and 2,8 mmol of sodium.

As both the amoxicillin and clavulanic acid components of AUGMENTIN are excreted by the kidneys, accumulation of both may occur in patients with renal insufficiency. In these cases monitoring of the serum levels and a reduction in the number of administrations of the suggested dosage may be required. Dosing adjustments are based on the maximum recommended level of amoxicillin.

Experience in a limited number of patients with varying degrees in renal insufficiency suggests that the following schedule of dosage based on the creatinine clearance of the patient, may be used as a guideline:

Creatinine Clearance	Dosage
> 30 ml/min	no dosage adjustment
10-30 ml/min	1,2 g AUGMENTIN stat and 600 mg 12 hourly
< 10 ml/min	1,2 g AUGMENTIN stat and 600 mg 24 hourly

SIDE EFFECTS:

Data from large clinical trials was used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e., those occurring at <1/10 000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

The following convention has been used for the classification of frequency:

very common (≥1/10)

common (≥1/100, <1/10)

uncommon (≥1/1 000, <1/100)

rare (≥1/10 000, <1/1 000)

very rare (<1/10 000).

Clinical trial data:

Infections and infestations:

Common: mucocutaneous candidiasis (including vaginitis, stomatitis, glossitis)

Blood and lymphatic system disorders:

Rare: reversible leucopenia (including neutropenia) and thrombocytopenia

Nervous system disorders:

Uncommon: dizziness, headache

Vascular disorders:

Rare: thrombophlebitis at the site of injection

Gastrointestinal disorders:

Common: diarrhoea

Uncommon: nausea, vomiting, indigestion, gastritis.

The incidence and severity of adverse effects, particularly nausea and diarrhoea, increased with the higher recommended dose and can be minimised by administering AUGMENTIN at the start of a meal. In addition, as these symptoms are especially related to the potassium clavulanate component, where these gastrointestinal symptoms occur and a higher concentration of amoxicillin is required, consideration should be given to administering the additional amoxicillin separately.

Hepatobiliary disorders:

Uncommon: a moderate rise in AST and/or ALT has been noted in patients treated with AUGMENTIN

Very rare: hepatitis and cholestatic jaundice.

Hepatic events may be severe and fatal. Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased.

Skin and subcutaneous tissue disorders:

Uncommon: skin rash, pruritus, urticaria

Rare: erythema multiforme.

Side effects reported from post-marketing spontaneous reports:

Blood and lymphatic system disorders:

Reversible agranulocytosis, haemolytic anaemia, prolongation of bleeding time and prothrombin time (increased INR).

Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

Immune system disorders:

Angioedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis.

Nervous system disorders:

Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Gastrointestinal disorders:

Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) (refer to WARNINGS AND SPECIAL PRECAUTIONS).

Hepatobiliary disorders:

Hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.

Hepatic events may be severe and fatal occurring predominantly in males and elderly patients, and may be associated with prolonged treatment. Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased.

Skin and subcutaneous tissue disorders:

Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP).

If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.

Renal and urinary disorders:

Interstitial nephritis, crystalluria (refer to KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Nausea, vomiting and diarrhoea may occur with overdosing. If encountered, gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically with attention to the water/electrolyte imbalance.

Amoxicillin may be removed from circulation by haemodialysis. The molecular weight, degree of protein binding and pharmacokinetic profile of clavulanic acid together with

information from a single patient with renal insufficiency all suggest that this compound may also be removed by haemodialysis.

During the administration of high doses of AUGMENTIN, adequate fluid intake and urinary output should be maintained to minimise the possibility of amoxicillin crystalluria. Amoxycillin crystalluria, in some cases leading to renal failure, has been observed (refer to WARNINGS AND SPECIAL PRECAUTIONS).

Amoxicillin has been reported to precipitate in bladder catheters after intravenous administration of large doses. A regular check of patency should be maintained.

IDENTIFICATION:

AUGMENTIN IV 0,6: White to off white powder in vials. When reconstituted a clear colourless to yellow solution.

AUGMENTIN IV 1,2: White to off white powder in vials. When reconstituted a clear colourless to yellow solution.

PRESENTATION:

AUGMENTIN IV 0,6: Clear glass vial fitted with a rubber stopper and tamper evident seal containing powder for injection in cartons of 10 vials.

AUGMENTIN IV 1,2: Clear glass vial fitted with a rubber stopper and a tamper evident seal containing powder for injection in cartons of 10 vials.

STORAGE INSTRUCTIONS:

AUGMENTIN IV should be stored in a cool, dry place at or below 25 °C.

IV Injection: Once reconstituted, the contents of the vials must be used within 20 minutes.

IV Infusion: For information on stability after reconstitution see the “Compatibility and stability” table and directions as presented under “DOSAGE AND DIRECTIONS FOR USE”.

Keep out of reach of children.

REGISTRATION NUMBER:

AUGMENTIN IV 0,6: U/20.1.2/45

AUGMENTIN IV 1,2: U/20.1.2/46

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithkline South Africa (Pty) Limited

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PACKAGE INSERT:

Date of registration: 14 February 1989

Date of most recent revision: 29 July 2016

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MANUFACTURER:

SmithKline Beecham Pharmaceuticals, Clarendon Road, Worthing, Sussex, UK

Botswana:

Augmentin IV 1,2 - Reg No B9325230 S2

Malawi:

Augmentin IV 0,6 – Reg No PMPB/PL270/17 POM

Augmentin IV 1,2 – Reg No PMPB/PL270/14 POM

Namibia:

Augmentin IV 0,6 - Reg No 90/20.1.2/001579 NS2

Augmentin IV 1,2 - Reg No 90/20.1.2/001580 NS2

Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

AUGMENTIN IV 0,6 Powder for injection

500 mg of amoxicillin and 100 mg clavulanic acid

AUGMENTIN IV 1,2 Powder for injection

1 000 mg of amoxicillin and 200 mg clavulanic acid

Read all of this leaflet carefully before you receive AUGMENTIN.

AUGMENTIN IV is not for self-medication, and must be administered by a healthcare professional.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

AUGMENTIN has been prescribed for you only, and should not be shared with other people. It may harm them, even if their symptoms are the same.

WHAT AUGMENTIN CONTAINS:

AUGMENTIN IV 0,6: contains the active substances 500 mg of amoxicillin and 100 mg clavulanic acid.

AUGMENTIN IV 1,2: contains the active substances 1 000 mg of amoxicillin and 200 mg clavulanic acid.

There are no other ingredients.

Sugar-free.

WHAT AUGMENTIN IS USED FOR:

AUGMENTIN is an antibiotic which works by killing bacteria that cause infections. It contains two active ingredients; a penicillin called amoxicillin and clavulanic acid.

AUGMENTIN IV is used to treat certain bacterial infections.

BEFORE YOU RECEIVE AUGMENTIN:

You should not receive AUGMENTIN if:

- you are allergic to amoxicillin, penicillin or cephalosporin**.** If you have had an allergic reaction (such as a rash) when taking an antibiotic, you should talk to your doctor before receiving AUGMENTIN
- you had jaundice (yellowing of the skin and/or eyes) or liver disease while taking/receiving AUGMENTIN.

Take special care with AUGMENTIN if:

- you or your child is under 12 years of age
- you develop a skin rash while receiving AUGMENTIN. Administration should be stopped

- you have glandular fever and are prescribed AUGMENTIN. Please tell your doctor before you receive the medicine
- you have liver or kidney problems. The dosage may need to be reduced or you may need to be given a different medicine
- you have a history of gastrointestinal disease
- you are on a low sodium (salt) diet
- you are not passing water regularly.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of AUGMENTIN or a different medicine.

Conditions you need to look out for:

AUGMENTIN can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are receiving AUGMENTIN, to reduce the risk of any problems. See POSSIBLE SIDE EFFECTS.

Blood and urine tests:

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are receiving AUGMENTIN. This is because AUGMENTIN can affect the results of these type of tests.

Pregnancy and breastfeeding:

You should not receive AUGMENTIN if you are pregnant or breastfeeding your baby**.**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving AUGMENTIN.

AUGMENTIN may reduce the efficacy of contraceptive pills. If you are taking a contraceptive pill you should talk to your doctor before receiving AUGMENTIN.

Taking other medicines with AUGMENTIN:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

It is particularly important that the doctor knows if you are taking the following medicines:

- allopurinol
- probenecid
- anti-coagulants (used to prevent blood clots) such as warfarin.

HOW AUGMENTIN IV WILL BE ADMINISTERED TO YOU:

The doctor or nurse will give you the recommended dose of AUGMENTIN, either by injection into a vein or by intravenous infusion.

AUGMENTIN must not be injected into a muscle or under the skin.

Your doctor will decide how much you need to receive each day and how many days you should receive it for. You will not normally be given AUGMENTIN for longer than 10 days without your doctor reviewing your treatment.

Remember to drink plenty of fluids such as water or non-alcoholic drinks, whilst receiving AUGMENTIN**.**

If there is anything you do not understand please ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:

AUGMENTIN can have side effects.

If you have any of the following symptoms after receiving AUGMENTIN, tell your doctor IMMEDIATELY:

- sudden wheeziness, shortness of breath, or chest tightness
- swelling of the face, lips, tongue, or other parts of the body
- suddenly feeling faint, especially upon standing up
- convulsions (fits or seizures)
- yellowing of the skin and/or eyes, or dark coloured urine. These symptoms may be accompanied by itching, fever, nausea, vomiting, loss of appetite and feeling generally unwell. These symptoms may not occur until several weeks after the end of treatment and can be severe

- blood in the urine which may be associated with a rash, fever, joint pain, or a reduction in passing water (urination)
- severe diarrhoea, which may be bloody, or contain mucus, and which may be accompanied by stomach cramps
- a rash with blisters that may cause the skin to peel, flake, or bleed
- unusual tiredness, headaches, being short of breath when exercising, dizziness, looking pale.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AUGMENTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, severe chills, sore throat or mouth ulcers. Unusual joint pains especially if accompanied by a rash
- the tongue may change colour to yellow, brown or black, and it may have a hairy appearance
- bleeding, or bruising, more easily than usual
- a rash where the spots (usually 0,5 cm to 2 cm in size) have a pink/red ring around the edge and a darker centre.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- mild rash, itching or hives (itchy lumps)
- indigestion
- headache
- dizziness
- diarrhoea (loose or watery bowel movements)

- nausea (feeling sick)
- vomiting (being sick)
- thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.

Symptoms such as indigestion, feeling sick and being sick can often be avoided by giving AUGMENTIN before food.

You may experience pain, redness or swelling at the injection site.

Not all side effects reported for AUGMENTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSING OF AUGMENTIN:

Store all medicines out of reach of children.

The expiry date of this medicine is printed on the label. Do not use the medicine after this date.

The medicine should be stored in a cool, dry place, at or below 25 °C.

PRESENTATION OF AUGMENTIN:

AUGMENTIN IV 0,6: Clear glass vial fitted with a rubber stopper and tamper evident seal containing powder for injection in cartons of 10 vials.

AUGMENTIN IV 1,2: Clear glass vial fitted with a rubber stopper and tamper evident seal containing powder for injection in cartons of 10 vials.

IDENTIFICATION OF AUGMENTIN:

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REGISTRATION NUMBER:

AUGMENTIN IV 0,6: U/20.1.2/45

AUGMENTIN IV 1,2: U/20.1.2/46

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Limited

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION

Date of registration: 14 February 1989

Date of most recent revision: 29 July 2016

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Pasiëntinligtingsbrosjure

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

AUGMENTIN IV 0,6 Poeier vir inspuiting

500 mg amoksisillien en 100 mg klavulaansuur

AUGMENTIN IV 1,2 Poeier vir inspuiting

1 000 mg amoksisillien en 200 mg klavulaansuur

Lees hierdie hele brosjure noukeurig deur voordat jy AUGMENTIN ontvang.

AUGMENTIN IV is nie vir selfmedikasie nie en moet deur ’n gesondheidsorgkundige toegedien word.

Hou hierdie brosjure. Dit mag nodig wees dat jy dit weer moet lees.

As jy nog vrae het, moet jy jou dokter of apteker asseblief vra.

AUGMENTIN is vir jou alleenlik voorgeskryf en moet nie aan ander mense gee word nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as joune.

WAT AUGMENTIN BEVAT:

AUGMENTIN IV 0,6: bevat as aktiewe bestanddele 500 mg amoksisillien en 100 mg klavulaansuur.

AUGMENTIN IV 1,2: bevat as aktiewe bestanddele 1 000 mg amoksisillien en 200 mg klavulaansuur.

Daar is geen ander bestanddele nie.

Suikervry.

WAARVOOR AUGMENTIN GEBRUIK WORD:

AUGMENTIN is ’n antibiotikum en werk deur bakterieë wat infeksies veroorsaak dood te maak. Dit bevat twee aktiewe bestanddele; amoksisillien en klavulaansuur.
AUGMENTIN IV word gebruik om sekere bakteriële infeksies te behandel.

VOORDAT JY AUGMENTIN KRY:

Jy moet AUGMENTIN nie kry nie as:

- jy allergies vir amoksisillien, penisillien of kefalosporien is. As jy ’n allergiese reaksie (soos ’n veluitslag) met ’n antibiotikum gehad het, moet jy met jou dokter praat voordat jy AUGMENTIN kry
- jy geelsug (geel verkleuring van die vel en/of oë) of ’n lewersiekte gehad het terwyl jy AUGMENTIN gebruik het.

Wees besonder versigtig met AUGMENTIN as:

- jy of jou kind jonger as 12 jaar is
- jy ’n veluitslag ontwikkel terwyl jy AUGMENTIN kry. Toediening moet gestaak word
- jy klierkoors het en AUGMENTIN is aan jou voorgeskryf. Sê asseblief vir die dokter voordat jy die medisyne kry
- jy lewer- of nierprobleme het. Dit kan nodig wees om die dosis te verlaag of om ander medisyne vir jou te gee
- jy ’n geskiedenis van gastro-intestinale siektes het
- jy ’n dieet met min natrium (sout) volg
- jy nie gereeld urineer nie.

In party gevalle kan jou dokter die tipe bakterieë wat jou infeksie veroorsaak laat identifiseer. Afhangende van die uitslae, kan ’n ander sterkte van AUGMENTIN of ander medisyne aan jou gegee word.

Toestande waarvoor opgelet moet word:

AUGMENTIN kan maak dat sekere bestaande toestande erger kan word, of kan ernstige newe-effekte veroorsaak. Dit is onder meer allergiese reaksies, stuiptrekkings (toevalle) en

inflammasie van die dikderm. Jy moet oplet na sekere simptome terwyl jy AUGMENTIN ontvang om die risiko vir enige probleme te verlaag. Kyk MOONTLIKE NEWE-EFFEKTE.

Bloed- en urientoetse:

As jy bloedtoetse (soos toetse van rooibloedselle of lewerfunksie) of urientoetse (vir glukose) ondergaan, moet jy vir die dokter of verpleegkundige sê dat jy AUGMENTIN ontvang. Dit is omdat AUGMENTIN die uitslae van hierdie tipes toetse kan beïnvloed.

Swangerskap en borsvoeding:

Jy moet AUGMENTIN nie ontvang as jy swanger is of jou baba borsvoed nie.

As jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgkundige om advies vra voordat jy AUGMENTIN ontvang.

AUGMENTIN kan die effektiwiteit van voorbehoedpille verminder. As jy voorbehoedpille drink, moet jy met jou dokter praat voordat jy AUGMENTIN ontvang.

Gebruik van ander medisyne saam met AUGMENTIN:

Sê altyd vir jou gesondheidsorgkundige as jy enige ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisyne in.)

Dit is veral belangrik dat die dokter moet weet as jy die volgende medisyne gebruik:

- allopurinol
- probenesied
- antikoagulante (om bloedklonte te voorkom) soos warfarien.

HOE AUGMENTIN IV AAN JOU GEGEE SAL WORD:

Die dokter of verpleegkundige sal die aanbevole dosis van AUGMENTIN aan jou gee, hetsy deur inspuiting in ’n aar of deur binneaarse infusie.

AUGMENTIN moet nie in ’n spier of onder die vel ingespuit word nie.

Jou dokter sal besluit hoeveel medisyne jy elke dag moet kry, en vir hoeveel dae jy dit moet kry. AUGMENTIN sal gewoonlik nie vir langer as 10 dae aan jou gegee word sonder dat jou dokter jou behandeling sal heroorweeg nie.

Onthou om baie vloeistowwe soos water of nie-alkoholiese drankies te drink terwyl jy AUGMENTIN ontvang.

As daar enigiets is wat jy nie verstaan nie, vra asseblief vir jou dokter of apteker.

MOONTLIKE NEWE-EFFEKTE:

AUGMENTIN kan newe-effekte veroorsaak.

As jy enige van die volgende simptome ervaar nadat jy AUGMENTIN ontvang het, moet jy jou dokter ONMIDDELIK skakel:

- skielike gehyg, kortasemheid of toe bors
- swelling van die gesig, lippe, tong of ander dele van die liggaam
- voel skielik flou, veral wanneer opgestaan word
- stuiptrekkings (toevalle of konvulsies)
- geel verkleuring van die vel en oë of donker urien. Hierdie simptome kan met jeuk, koors, naarheid, braking, verlies van eetlus en ’n algemeen siek gevoel gepaardgaan. Hierdie simptome kan eers etlike weke na die einde van die behandeling voorkom en kan ernstig wees
- bloed in die urien wat met veluitslag, koors, gewrigspyn of ’n vermindering in die volume urien kan gepaardgaan
- erge diarree, wat bloederig kan wees, of slym bevat, en wat met maagkrampe gepaardgaan
- ’n veluitslag met blase wat kan veroorsaak dat die vel afdop, afskilfer of bloei
- ongewone moegheid, hoofpyn, kortasemheid tydens oefening, duiseligheid, bleekheid.

Dit is almal baie ernstige newe-effekte. As jy dit ervaar, kan dit wees dat jy ’n ernstige allergiese reaksie teenoor AUGMENTIN het. Jy mag dringende mediese aandag of hospitalisasie nodig hê.

Sê dadelik vir jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal as jy enige van die volgende opmerk:

- koors, erge koue rillings, seer keel of mondsere. Ongewone gewrigspyn veral as dit met ’n veluitslag gepaardgaan
- die tong kan van kleur verander na geel, bruin of swart, en dit kan ’n harige voorkoms hê
- bloeding of kneusing wat makliker as gewoonlik gebeur
- ’n uitslag waar die kolle (gewoonlik 0,5 cm tot 2 cm in grootte) ’n pienk/rooi ring om die rand en ’n donkerder middel het.

Dit is almal ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Sê vir jou dokter as jy enige van die volgende opmerk:

- ligte veluitslag, jeuk of galbulte (jeukende bulte)
- slegte spysvertering
- hoofpyn
- duiseligheid
- diarree (los of waterige stoelgang)
- naarheid (voel mislik)
- braking (opbring)
- sproei (’n fungusinfeksie van die vagina, mond of die velplooie). Jy kan middels vir sproei van jou dokter of apteker kry.

Simptome soos slegte spysvertering, naarheid en braking kan dikwels vermy word deur AUGMENTIN voor voedsel te gee.

Jy kan pyn, rooiheid of swelling by die plek van die inspuiting ervaar.

Nie al die newe-effekte wat vir AUGMENTIN aangemeld is, is in hierdie brosjure opgeneem nie. As jou algemene gesondheidstoestand vererger of as jy newe-effekte ervaar terwyl jy hierdie medisyne kry, moet jy jou dokter, apteker of ander gesondheidsorgkundige om advies raadpleeg.

As jy enige newe-effekte opmerk wat nie in hierdie brosjure genoem word nie, moet jy jou dokter of apteker asseblief in kennis stel.

BEWARING EN WEGDOENING VAN AUGMENTIN:

Hou alle medisyne buite bereik van kinders.

Die vervaldatum van hierdie medisyne is op die etiket gedruk. Die medisyne moet nie na hierdie vervaldatum gebruik word nie.

Die medisyne moet op ’n koel, droë plek by of benede 25 °C gebêre word.

AANBIEDING VAN AUGMENTIN:

AUGMENTIN IV 0,6: Helder glasflessie met rubber prop en peuterbestande seël wat poeier vir inspuiting in kartonne met 10 flessies bevat.

AUGMENTIN IV 1,2: Helder glasflessie met rubber prop en peuterbestande seël wat poeier vir inspuiting in kartonne met 10 flessies bevat.

IDENTIFIKASIE VAN AUGMENTIN:

AUGMENTIN IV 0,6: Wit tot naaswit poeier in flessies. Helder kleurlose tot geel oplossing wanneer aangemaak.

AUGMENTIN IV 1,2: Wit naaswit poeier in flessies. Helder kleurlose tot geel oplossing wanneer aangemaak.

REGISTRASIENOMMER:

AUGMENTIN IV 0,6: U/20.1.2/45

AUGMENTIN IV 1,2: U/20.1.2/46

NAAM EN ADRES VAN HOUER VAN REGISTRASIE:

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