

# Package leaflet - information for the user

## Augmentin-Duo 400 mg/57 mg/5 ml Powder for Oral Suspension

### Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for them.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine is usually prescribed for a baby or child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Augmentin is and what it is used for
2. What you need to know before you give Augmentin
3. How to give Augmentin
4. Possible side effects
5. How to store Augmentin
6. Contents of the pack and other information

#### 1 WHAT AUGMENTIN IS AND WHAT IT IS USED FOR

Augmentin is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Augmentin is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

#### 2 WHAT YOU NEED TO KNOW BEFORE YOU GIVE AUGMENTIN

Do not give your child Augmentin:

- if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
  - if they have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
  - if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- Do not give Augmentin to your child if any of the above apply to your child. If you are not sure, talk to their doctor or pharmacist before giving Augmentin.

Take special care with Augmentin

Check with their doctor, pharmacist or nurse before giving your child this medicine if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Augmentin.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child 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 your child is taking Augmentin, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

#### Blood or urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests, let the doctor or nurse know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

#### Other medicines and Augmentin

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin. If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed.

Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. Augmentin can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

#### Pregnancy, breast-feeding and fertility

If your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

#### Augmentin contains aspartame and maltodextrin:

- Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3 HOW TO GIVE AUGMENTIN

Always give this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

#### Adults and children weighing 40 kg or over

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

#### Children weighing less than 40 kg

All doses are worked out depending on the child's bodyweight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. You should use this to give the correct dose to your baby or child.
- Recommended dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

#### Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

#### How to give Augmentin

- Always shake the bottle well before each dose
- Give at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.

- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

#### If you give more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

#### If you forget to give Augmentin

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose.

#### If your child stops taking Augmentin

Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. If you have any further questions on the use of this product, ask your doctor pharmacist or nurse.

#### 4 POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

#### Conditions you need to look out for

##### Allergic reactions:

- skin rash
  - inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
  - fever, joint pain, swollen glands in the neck, armpit or groin
  - swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
  - collapse.
- Contact a doctor immediately if your child gets any of these symptoms. Stop taking Augmentin.

##### Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

→ Contact your doctor as soon as possible for advice if your child gets these symptoms.

##### Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses

→ if affected take Augmentin before food.

- vomiting
- diarrhoea (in children).

##### Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

##### Uncommon side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver.

##### Rare side effects

These may affect up to 1 in 1000 people

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – *erythema multiforme*)

→ if you notice any of these symptoms contact a doctor urgently.

##### Rare side effects that may show up in blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

##### Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:
  - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
  - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
  - a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).
- Contact a doctor immediately if your child gets any of these symptoms.
- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Augmentin or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing.

Side effects that may show up in blood or urine tests:

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine.

##### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5 HOW TO STORE AUGMENTIN

Store in the original package in order to protect from moisture.

The dry powder should be stored in the original container.

Do not store above 25 °C.

Reconstituted suspensions should be stored at 2 °C – 8 °C (but not frozen) for up to seven days.

Keep out of the reach and sight of children.

Do not use Augmentin-Duo Suspension after the expiry date which is stated on the carton and bottle label after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6 CONTENTS OF THE PACK AND OTHER INFORMATION

##### What Augmentin contains

The active substances are amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 mg of clavulanic acid. Amoxicillin is an antibiotic and clavulanic acid is a beta-lactamase inhibitor, which is commonly combined with the penicillin group antibiotics to overcome antibiotic resistance.

When reconstituted, each 5ml of oral suspension contains amoxicillin trihydrate equivalent to 400 mg of amoxicillin and potassium clavulanate equivalent to 57 mg of clavulanic acid.

The other ingredients in this medicine are: Crospovidone, Croscarmellose sodium, Xanthan gum, Colloidal anhydrous silica, Magnesium stearate, Sodium benzoate, Aspartame (E951), Strawberry flavour (containing maltodextrin), Silicon dioxide

**What Augmentin looks like and contents of the pack**

Clear glass bottle containing a dry white powder with yellowish grains and a characteristic odour for reconstitution to 35ml or 70ml.

This may be supplied with a plastic measuring spoon or plastic measuring cup or dosing syringe.

Not all pack sizes may be marketed

**Parallel Product Authorisation Holder and Manufacturer****Product procured from within the EU by the Parallel Product Authorisation Holder:**

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

**Manufacturer:**

SmithKline Beecham Pharmaceuticals, Clarendon Road, Worthing, West Sussex, BN14 8QH, United Kingdom.

**Repackaged by:**

Cast Healthcare Ltd, Unit B6 The Business Centre, 5-7 Tobermore Road, Draperstown, BT45 7AG, UK

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria – Augmentin,  
 Cyprus – Augmentin,  
 Czech Republic- Augmentin Duo  
 Estonia – Augmentin  
 Finland – Augmentin,  
 Greece – Augmentin  
 Hungary- Augmentin Duo  
 Iceland – Augmentin  
 Ireland – Augmentin Duo  
 Italy – Augmentin, Clavulin  
 Latvia – Augmentin  
 Malta – Augmentin,  
 Poland – Augmentin  
 Portugal – Augmentin Duo,  
 Romania – Augmentin BIS  
 Slovak Republic- Augmentin DUO  
 Slovenia – Augmentin  
 Sweden – SpektramoX  
 United Kingdom – Augmentin Duo

**This leaflet was last approved in April 2014**

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**Advice/medical education**

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

**Instructions for reconstitution**

Check cap seal is intact before using. Shake bottle to loosen powder. Add volume of water (as indicated below) invert and shake well. Alternatively shake bottle to loosen powder then fill the bottle with water to just below the line on the bottle or label. Invert and shake well, then top up with water exactly to the line. Invert and again shake well.

Strength	Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral suspension (ml)
400mg/57mg/5ml	32	35
	64	70

Shake the bottle well before each dose.



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Take special care with Augmentin

Check with their doctor, pharmacist or nurse before giving your child this medicine if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

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In some cases, your doctor may investigate the type of bacteria that is causing your child’s infection. Depending on the results, your child may be given a different strength of Augmentin or a different medicine. Conditions you need to look out for.

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- Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3 HOW TO GIVE AUGMENTIN

Always give this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

#### Adults and children weighing 40 kg or over

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

#### Children weighing less than 40 kg

All doses are worked out depending on the child's bodyweight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. You should use this to give the correct dose to your baby or child.
- Recommended dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

#### Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

#### How to give Augmentin

- Always shake the bottle well before each dose
- Give at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.

- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

#### If you give more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

#### If you forget to give Augmentin

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose.

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Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. If you have any further questions on the use of this product, ask your doctor pharmacist or nurse.

#### 4 POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

#### Conditions you need to look out for

##### Allergic reactions:

- skin rash
- inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- collapse.

→ **Contact a doctor immediately if your child gets any of these symptoms. Stop taking Augmentin.**

#### Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

→ **Contact your doctor as soon as possible for advice if your child gets these symptoms.**

#### Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses

→ if affected take Augmentin before food.

- vomiting
- diarrhoea (in children).

#### Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

#### Uncommon side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver.

#### Rare side effects

These may affect up to 1 in 1000 people

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – *erythema multiforme*)

→ if you notice any of these symptoms contact a doctor urgently.

#### Rare side effects that may show up in blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

#### Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions (see above)
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#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine

#### 5 HOW TO STORE AUGMENTIN

Store in the original package in order to protect from moisture.

The dry powder should be stored in the original container.

Do not store above 25 °C.

Reconstituted suspensions should be stored at 2 °C – 8 °C (but not frozen) for up to seven days.

Keep out of the reach and sight of children.

Do not use Augmentin-Duo Suspension after the expiry date which is stated on the carton and bottle label after EXP.

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Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6 CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Augmentin contains

The active substances are amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 mg of clavulanic acid. Amoxicillin is an antibiotic and clavulanic acid is a beta-lactamase inhibitor, which is commonly combined with the penicillin group antibiotics to overcome antibiotic resistance.

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Clear glass bottle containing a dry white powder with yellowish grains and a characteristic odour for reconstitution to 35ml or 70ml.

This may be supplied with a plastic measuring spoon or plastic measuring cup or dosing syringe.

Not all pack sizes may be marketed

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**Manufacturer:**

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**Repackaged by:**

IMED Pharma Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

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 Hungary- Augmentin Duo  
 Iceland – Augmentin  
 Ireland – Augmentin Duo  
 Italy – Augmentin, Clavulin  
 Latvia – Augmentin  
 Malta – Augmentin,  
 Poland – Augmentin  
 Portugal – Augmentin Duo,  
 Romania – Augmentin BIS  
 Slovak Republic- Augmentin DUO  
 Slovenia – Augmentin  
 Sweden – SpektramoX  
 United Kingdom – Augmentin Duo

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3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

**Instructions for reconstitution**

Check cap seal is intact before using. Shake bottle to loosen powder. Add volume of water (as indicated below) invert and shake well. Alternatively shake bottle to loosen powder then fill the bottle with water to just below the line on the bottle or label. Invert and shake well, then top up with water exactly to the line. Invert and again shake well.

Strength	Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral suspension (ml)
400mg/57mg/5ml	32	35
	64	70

Shake the bottle well before each dose.