

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Augmentin-Duo® 400mg/57mg/5ml**  
**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.

The name of your medicine is Augmentin-Duo 400mg/57mg/5ml, Powder for Oral Suspension but will be referred to as Augmentin-Duo Suspension throughout this leaflet.

**What is in this leaflet:**

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

**1. WHAT AUGMENTIN-DUO SUSPENSION IS AND WHAT IT IS USED FOR**

Augmentin-Duo Suspension 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-Duo Suspension 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-DUO SUSPENSION**

**Do not give your child Augmentin-Duo Suspension:**

- 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-Duo Suspension 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-Duo Suspension.

**Take special care with Augmentin-Duo Suspension**

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-Duo Suspension.

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-Duo Suspension or a different medicine.

**Conditions you need to look out for**

Augmentin-Duo Suspension 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-Duo Suspension, 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-Duo Suspension. This is because Augmentin-Duo Suspension can affect the results of these types of tests.

**Other medicines and Augmentin-Duo Suspension**

Tell your doctor or pharmacist if your child is taking or 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-Duo Suspension, 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-Duo Suspension.

If medicines to help stop blood clots (such as warfarin) are taken with Augmentin-Duo Suspension then extra blood tests may be needed.

Augmentin-Duo Suspension 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-Duo Suspension contains aspartame and maltodextrin:**

- Augmentin-Duo Suspension contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'
- Augmentin-Duo Suspension 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-DUO SUSPENSION**

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

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

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

**Children weighing less than 40kg**

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

- Your doctor will advise you how much Augmentin-Duo Suspension 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 – 25mg/3.6mg to 45mg/6.4mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70mg/10mg 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-Duo Suspension**

- 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-Duo Suspension for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

**If you give more Augmentin-Duo Suspension than you should**

If you give your child too much Augmentin-Duo Suspension, 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-Duo Suspension**

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-Duo Suspension**

Keep giving your child Augmentin-Duo Suspension 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 medicine, 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-Duo Suspension.**

### 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-Duo Suspension 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 your 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-Duo Suspension 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-DUO SUSPENSION

Don't use this medicine if the expiry date printed on the bottle and carton has passed. If any medicine is left after seven days, return it to your pharmacist.

Do not store the dry powder above 25°C. Keep the container tightly closed and store in the original package.

After reconstitution store in a refrigerator between 2-8°C and use suspension within 7 days. Do not freeze.

### Keep all medicines out of the reach and sight of children

If your doctor asks you to stop giving this medicine, or if for any other reason there is some medicine left over, please return it to the pharmacist.

Remember, this medicine is just for your child. Do not give it to anyone else. It may not be suitable for them, even if their symptoms seem to be the same as your child's.

**Put this leaflet somewhere safe until your child has finished taking all the medicine.**

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Augmentin-Duo Suspension contains

Augmentin-Duo Suspension contains amoxicillin trihydrate equivalent to 400mg amoxicillin and potassium clavulanate equivalent to 57mg clavulanic acid in every 5ml. Both of these ingredients are antibiotics.

The other ingredients are: crospovidone, carmellose sodium, xanthan gum, colloidal anhydrous silica, magnesium stearate, sodium benzoate (E211), aspartame (E951), hydrated colloidal silica and strawberry flavour.

### What Augmentin-Duo Suspension looks like and contents of the pack

Augmentin-Duo Suspension is a dry white powder for reconstitution with off-white grains and a characteristic odour.

Your child's Augmentin-Duo Suspension comes in a bottle containing 35ml of an off-white suspension.

**Manufactured by:** Glaxo Wellcome Production Unite de Production de Terras II Zone Industrielle de la Peyrenniere F-53101 Mayenne France.

and  
SmithKline Beecham Pharmaceuticals, Clarendon Road Worthing, West Sussex, BN14 8QH, UK.

**Procured from within the EU and repackaged by PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**POM**

**Augmentin-Duo® 400/57mg/5ml Powder for Oral Suspension PPA No: 1328/50/2**

Leaflet date: 22.06.2015

Augmentin-Duo® is a registered trademark of GlaxoSmithKline group of companies.

### 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 fill the bottle with water to just below the mark on bottle label, invert and shake well, Then top up with water exactly to the the black arrow that has 'Livello Liquido' stated on it, 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

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**Augmentin-Duo 400mg/57mg/5ml**  
**Powder for Oral Suspension**  
**(amoxicillin/clavulanic acid)**

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The name of your medicine is AUGMENTIN-DUO® 400mg/57mg/5ml, Powder for Oral Suspension but will be referred to as Augmentin-Duo Suspension throughout the remainder of this leaflet.

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**1. What Augmentin-Duo Suspension is and what it is used for**

Augmentin-Duo Suspension 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-Duo Suspension 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
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**2. What you need to know before you give Augmentin-Duo Suspension**

**Do not give your child Augmentin-Duo Suspension:**

- 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-Duo Suspension 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-Duo Suspension.

**Take special care with Augmentin-Duo Suspension**

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-Duo Suspension.

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-Duo Suspension or a different medicine.

**Conditions you need to look out for**

Augmentin-Duo Suspension 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-Duo Suspension, to reduce the risk of any problems. See 'Conditions you need to look out for' in **Section 4**.

**Blood and urine tests**

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

**Other medicines and Augmentin-Duo Suspension**

Tell your doctor or pharmacist if your child is taking or 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-Duo Suspension, 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-Duo Suspension.

If medicines to help stop blood clots (such as warfarin) are taken with Augmentin-Duo Suspension then extra blood tests may be needed.

Augmentin-Duo Suspension 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-Duo Suspension contains aspartame and maltodextrin:**

- Augmentin-Duo Suspension contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'
- Augmentin-Duo Suspension 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-Duo Suspension**

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

**Adults and children weighing 40kg and over**

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

**Children weighing less than 40kg**

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

- Your doctor will advise you how much Augmentin-Duo Suspension 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 – 25mg/3.6mg to 45mg/6.4mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70mg/10mg 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 changed. 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-Duo Suspension**

- 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-Duo Suspension for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

**If you give more Augmentin-Duo Suspension than you should**

If you give your child too much Augmentin-Duo Suspension, 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-Duo Suspension**

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 stop taking Augmentin-Duo Suspension**

Keep giving your child Augmentin-Duo Suspension 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-Duo Suspension.**

### 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-Duo Suspension 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 your blood test:

- 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, particular 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-Duo Suspension 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 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-Duo Suspension

Don't use this medicine if the expiry date printed on the bottle and carton has passed. If any medicine is left after seven days, return it to your pharmacist.

Do not store the dry powder above 25°C. Keep the container tightly closed and store in the original package.

After reconstitution store in a refrigerator between 2-8°C and use suspension within 7 days. Do not freeze.

## Keep all medicines out of the reach and sight of children

If your doctor asks you to stop giving this medicine, or if for any other reason there is some medicine left over, please return it to the pharmacist.

Remember, this medicine is just for your child. Do not give it to anyone else. It may not be suitable for them, even if their symptoms seem to be the same as your child's.

**Put this leaflet somewhere safe until your child has finished taking all the medicine.**

## 6. Contents of the pack and other information

### What Augmentin-Duo Suspension contains and its package

Augmentin-Duo Suspension contains amoxicillin trihydrate equivalent to 400mg amoxicillin and potassium clavulanate equivalent to 57mg clavulanic acid in every 5ml. Both of these ingredients are antibiotics.

The other ingredients in this medicine are: crospovidone, carmellose sodium, xanthan gum, colloidal anhydrous silica, magnesium stearate, sodium benzoate (E211), aspartame (E951), strawberry flavour and silicon dioxide.

Dry white powder for reconstitution with off-white grains and a characteristic odour.

Your child's Augmentin-Duo Suspension comes in a bottle containing 70ml of an off-white liquid mixture called a suspension.

**Manufactured by:** SmithKline Beecham Pharmaceuticals, Worthing (UK) or Glaxo Wellcome Production, Mayenne France.

**Procured from within the EU and repackaged by PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**PPA No: 1328/50/2** **POM**

**AUGMENTIN-DUO 400/57mg/5ml Powder for Oral Suspension**

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Leaflet date: 22.06.2015

### 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
	127	140