

PACKAGE LEAFLET INFORMATION FOR THE PATIENT – SPOON

PHENOXYMETHYLPENICILLIN 125MG/5ML AND 250MG/5ML ORAL SOLUTION SUGAR FREE

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist (chemist).**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any of the side effects, talk to your doctor or pharmacist, this includes possible side effects not listed in this leaflet. See section 4.**

IN THIS LEAFLET

1. What Phenoxyethylpenicillin Oral Solution Sugar Free is and what it is used for
2. What you need to know before you take Phenoxyethylpenicillin Oral Solution Sugar Free
3. How to take Phenoxyethylpenicillin Oral Solution sugar Free
4. Possible side effects
5. How to store Phenoxyethylpenicillin Oral solution Sugar Free
6. Contents of the pack and other information

1. WHAT PHENOXYMETHYLPENICILLIN ORAL SOLUTION SUGAR FREE IS AND WHAT IT IS USED FOR

Phenoxyethylpenicillin Oral Solution Sugar Free is available in two strengths as a powder for reconstitution. The powder for reconstitution is prepared by the pharmacist before dispensing by adding water to the powder to give 100ml of oral solution. The strength you are given will be decided by your doctor.

Phenoxyethylpenicillin, the active ingredient, is an antibiotic, which belongs to a group of medicines called penicillins, which are used to kill bacteria that cause infections in your body. Your medicine is used to:

- treat bacterial infections of the ear, throat, respiratory tract, skin and soft tissues
- prevent infections such as rheumatic fever or chorea recurring
- prevent pneumococcal infection (e.g. in asplenia and in patients with sickle cell disease).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PHENOXYMETHYLPENICILLIN ORAL SOLUTION SUGAR FREE

Do not take Phenoxyethylpenicillin Oral Solution Sugar Free if:

- You have ever had a bad reaction or allergic reaction to any penicillin-type antibiotic including cephalosporin drugs
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic
- You are allergic to any of the ingredients contained in this medicine

Warnings and precautions

- You suffer from any stomach problems, e.g. vomiting
- You suffer from any kidney problems
- You suffer from allergies and/or asthma

Other medicines and Phenoxyethylpenicillin Oral Solution Sugar Free:

Your medicine may interfere with other medicines that you may be taking. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines even those not prescribed, including herbal and homeopathic remedies.

Talk to your doctor or pharmacist if you are taking:

- Methotrexate (a drug used to treat cancers and psoriasis)
- Some other antibiotics (tetracyclines, erythromycin, neomycin and chloramphenicol have been reported to reduce the effect of penicillin)
- Sulfinpyrazone or probenecid (medicines used to treat gout)
- Anti-coagulants (e.g. warfarin - to prevent blood clots)
- Oral typhoid vaccine (penicillin can stop this from working)

Phenoxyethylpenicillin Oral Solution Sugar Free with food and drink

Guar gum (used as a thickening agent and normally found in puddings and ice-cream and benefiber) can reduce the absorption of phenoxyethylpenicillin.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you 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

This medicine should not affect your ability to drive or to use machinery.

Important information about some of the ingredients in your medicine

Ponceau 4R (E124) and sunset yellow (E110)

Can cause allergic type reactions including asthma. Such allergies are common in those people who are allergic to aspirin.

Sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PHENOXYMETHYLPENICILLIN ORAL SOLUTION SUGAR FREE

Follow all directions given to you by your doctor or pharmacist. Their directions may differ from the information contained in this leaflet. The pharmacist's label should tell you how much to take and how often. If it does not, or you are not sure, check with your doctor or pharmacist.

How much of your medicine to take

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

The dose will depend on the patient and will be decided by your doctor.

The usual doses for each age group are as follows:

Adults including the elderly and children over 12 years

250mg to 500mg every six hours (one to two 5ml spoonfuls of 250mg/5ml)

Children

Infants (up to 1 year): 62.5mg every 6 hours

1- 5 years: 125mg every six hours (one 5ml spoonful of 125mg/5ml)

6 – 12 years: 250mg every six hours (one 5ml spoonful of 250mg/5ml or two 5ml spoonfuls of 125 mg/5ml)

For preventing the recurrence of rheumatic fever or chorea:

The usual dose is 250mg twice daily on a continuing basis.

For the prevention of infection in patients without a spleen or patients with sickle cell disease:

For adults and children over 12 years, the dosage is 500mg every 12 hours.

For children aged between 6 and 12 years, the dosage is 250mg every 12 hours and for children below 5 years, the dosage is 125mg every 12 hours.

For children over 12 years the dose should not exceed the maximum adult doses.

For elderly, the dosage is as for the adult. The dosage should be lowered in poor renal function.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed by your doctor.
- Dosage might be changed by your doctor if you have liver problems along with kidney problem.

When to take your medicine

Phenoxymethylpenicillin Oral Solution Sugar Free is usually prescribed to be taken four times a day. It is best to take it as evenly spaced as possible.

Take this medicine when your stomach is empty. This means at least 30mins before food and preferably not less than two hours after food.

If you take more Phenoxymethylpenicillin Oral Solution Sugar Free than you should

If you accidentally take too much medicine, contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Phenoxymethylpenicillin Oral Solution Sugar Free

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. DO NOT take a double dose to make up for the dose you have missed.

If you stop taking your medicine

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your condition may re-occur or get worse.

4. POSSIBLE SIDE EFFECTS

Like all medicines phenoxymethylpenicillin can cause side effects although not everybody gets them.

STOP taking the medicine and tell your doctor IMMEDIATELY if you experience any of the following:

- an allergic reaction - symptoms may include: shortness of breath, skin rash or itching, hives, swelling of the skin (especially of the lips, face or tongue), chills or fever, painful joints
- severe peeling/blistering of the skin
- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema)
- seizures
- profuse watery diarrhoea usually with blood and mucus, stomach pain and fever

Tell your doctor or pharmacist if you notice any of the following and they worry you.

- stomach pain or cramps, nausea (feeling sick), vomiting (being sick) and diarrhoea
- sore mouth

- hepatitis
- convulsions
- black hairy tongue
- pins and needles or numbness
- sore throats, infections, or fever (may be caused by low white blood cells)
- problems with blood clotting (unusual bleeding or bruising)
- anaemia (may cause lack of energy or tiredness)
- kidney problems, which might cause blood in the urine or reduced amounts of urine
- jaundice – yellowing of skin or whites of the eyes

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, you should contact your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PHENOXYMETHYLPENICILLIN ORAL SOLUTION SUGAR FREE

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Expiry date

Do not use your medicine after the expiry date which is stated on the label. The expiry date, listed as “expiry” on the label, refers to the last day of that month.

Storage conditions

Phenoxymethylpenicillin Oral Solution Sugar Free should be stored for up to 7 days in a refrigerator. Keep it in the pack in which it was given to you. Do not transfer your medicine to another container.

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.

If your doctor tells you to stop your treatment return any left over to the pharmacist. Only keep it if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Phenoxymethylpenicillin Oral Solution Sugar Free contains:

Active ingredient: Each 5ml spoonful of oral solution contains 125mg or 250mg of phenoxymethylpenicillin as phenoxymethylpenicillin potassium.

Other ingredients: sodium benzoate (E211), saccharin sodium, trusil orange flavour, orange colour (containing sunset yellow (E110) and ponceau 4R (E124)), sorbitol 60W (E420) and mono ammonium glycyrrhizate.

What Phenoxymethylpenicillin looks like and contents of the pack

Unconstituted powder: An off white to pale pink dry granular powder.

Reconstituted solution: A clear orange solution with an orange odour.

Phenoxymethylpenicillin Oral Solution is available in a size of 100ml on reconstitution.

The product licence holder and manufacturer is:

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Your medicine is distributed by:

*

PL 30464/0070 and PL 30464/0071

This leaflet was last revised October 2015

*Kent Pharmaceuticals Limited,
Repton Road, Measham, DE12 7DT, U.K.

*Athlone Pharmaceuticals Limited,
Ballymurray, Co. Roscommon, Ireland. (not commercialised)

*Almus Pharmaceuticals
43 Cox Lane, Chessington, KT9 1SN, UK.

**PACKAGE LEAFLET INFORMATION FOR THE PATIENT LEAFLET –
SYRINGE**

**PHENOXYMETHYLPENICILLIN 125MG/5ML AND 250MG/5ML ORAL
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- prevent infections such as rheumatic fever or chorea recurring
- prevent pneumococcal infection (e.g. in asplenia and in patients with sickle cell disease).

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- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic
- You are allergic to any of the ingredients contained in this medicine

Warnings and precautions

- You suffer from any stomach problems, e.g. vomiting
- You suffer from any kidney problems
- You suffer from allergies and/or asthma

Other medicines and Phenoxyethylpenicillin Oral Solution Sugar Free:

Your medicine may interfere with other medicines that you may be taking. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines even those not prescribed, including herbal and homeopathic remedies.

Talk to your doctor or pharmacist if you are taking:

- Methotrexate (a drug used to treat cancers and psoriasis)
- Some other antibiotics (tetracyclines, erythromycin, neomycin and chloramphenicol have been reported to reduce the effect of penicillin)
- Sulfinpyrazone or probenecid (medicines used to treat gout)
- Anti-coagulants (e.g. warfarin - to prevent blood clots)
- Oral typhoid vaccine (penicillin can stop this from working)

Phenoxyethylpenicillin Oral Solution Sugar Free with food and drink

Guar gum (used as a thickening agent and normally found in puddings and ice-cream and benefiber) can reduce the absorption of phenoxyethylpenicillin.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you 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

This medicine should not affect your ability to drive or to use machinery.

Important information about some of the ingredients in your medicine**Ponceau 4R (E124) and sunset yellow (E110)**

Can cause allergic type reactions including asthma. Such allergies are common in those people who are allergic to aspirin.

Sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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TO THE PHARMACIST: INSTRUCTIONS FOR RECONSTITUTION OF THE POWDER

1. Remove the cap and add the correct volume of potable water (85mls for the 125mg/5ml strength of product and 84mls for the 250mg/5ml strength of product)
2. Replace the cap and shake gently to avoid foaming.
3. Remove the cap once more and place the adaptor (Fig 1) into the bottle opening. The adaptor should not be removed at any stage.
4. Replace the cap, do not shake any further.

TO THE PATIENT: INSTRUCTIONS FOR USE OF THE SYRINGE

1. Remove the cap and if necessary push the adaptor into the neck of the bottle (Fig 1).
2. Push the plunger of the syringe to remove all the air.
3. Insert the syringe into the adaptor until it is firmly in place (Fig 2).
4. While holding the bottle and syringe shake the contents gently.
5. While holding the bottle, turn the entire assembly upside down.
6. While supporting the syringe draw off the required amount of medicine into the syringe (Fig 3).
7. Turn the assembly back up the right way and remove the syringe from the bottle.
8. Replace the cap onto the bottle.

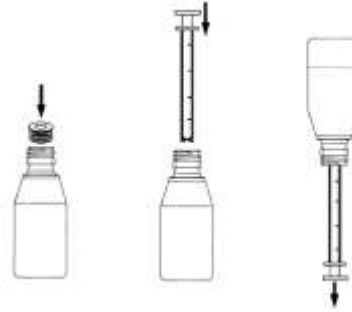


Fig 1

Fig 2

Fig 3

Administer the dose by introducing the tip of the syringe into the mouth of the infant/child, then apply a light pressure on the plunger to slowly release the solution. Keep it out of the reach of children.

Note: For subsequent dosage follow steps 3 and 4 above, before shaking in order to prevent leakage.

How much of your medicine to take

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

The dose will depend on the patient and will be decided by your doctor.

The usual doses for each age group are as follows:

Adults including the elderly and children over 12 years

250mg to 500mg every six hours (5ml to 10ml of 250mg/5ml)

Children

Infants (up to 1 year): 62.5mg every 6 hours

1- 5 years: 125mg every six hours (5ml of 125mg/5ml)

6 – 12 years: 250mg every six hours (5ml of 250mg/5ml or 10ml of 125 mg/5ml)

For preventing the recurrence of rheumatic fever or chorea:

The usual dose is 250mg twice daily on a continuing basis.

For the prevention of infection in patients without a spleen or patients with sickle cell disease:

For adults and children over 12 years, the dosage is 500mg every 12 hours.

For children aged between 6 and 12 years, the dosage is 250mg every 12 hours and for children below 5 years, the dosage is 125mg every 12 hours.

For children over 12 years the dose should not exceed the maximum adult doses.

For elderly, the dosage is as for the adult. The dosage should be lowered in poor renal function.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed by your doctor.
- Dosage might be changed by your doctor if you have liver problems along with kidney problem.

When to take your medicine

Phenoxymethylpenicillin Oral Solution Sugar Free is usually prescribed to be taken four times a day. It is best to take it as evenly spaced as possible.

Take this medicine when your stomach is empty. This means at least 30mins before food and preferably not less than two hours after food.

If you take more Phenoxymethylpenicillin Oral Solution Sugar Free than you should

If you accidentally take too much medicine, contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Phenoxymethylpenicillin Oral Solution Sugar Free

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. DO NOT take a double dose to make up for the dose you have missed.

If you stop taking your medicine

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your condition may re-occur or get worse.

4. POSSIBLE SIDE EFFECTS

Like all medicines phenoxymethylpenicillin can cause side effects although not everybody gets them.

STOP taking the medicine and tell your doctor IMMEDIATELY if you experience any of the following:

- an allergic reaction - symptoms may include: shortness of breath, skin rash or itching, hives, swelling of the skin (especially of the lips, face or tongue), chills or fever, painful joints
- severe peeling/blistering of the skin
- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema)
- seizures
- profuse watery diarrhoea usually with blood and mucus, stomach pain and fever

Tell your doctor or pharmacist if you notice any of the following and they worry you.

- stomach pain or cramps, nausea (feeling sick), vomiting (being sick) and diarrhoea
- sore mouth
- Hepatitis
- convulsions
- black hairy tongue
- pins and needles or numbness
- sore throats, infections, or fever (may be caused by low white blood cells)
- problems with blood clotting (unusual bleeding or bruising)
- anaemia (may cause lack of energy or tiredness)
- kidney problems, which might cause blood in the urine or reduced amounts of urine
- jaundice – yellowing of skin or whites of the eyes

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, you should contact your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more

information on the safety of this medicine.

5. HOW TO STORE PHENOXYMETHYLPENICILLIN ORAL SOLUTION SUGAR FREE

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Expiry date

Do not use your medicine after the expiry date which is stated on the label. The expiry date, listed as “expiry” on the label, refers to the last day of that month.

Storage conditions

Phenoxymethylpenicillin Oral Solution Sugar Free should be stored for up to 7 days in a refrigerator. Keep it in the pack in which it was given to you. Do not transfer your medicine to another container.

If your doctor tells you to stop your treatment return any left over to the pharmacist. Only keep it if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Phenoxymethylpenicillin Oral Solution Sugar Free contains:

Active ingredient: Each 5ml of oral solution contains 125mg or 250mg of phenoxymethylpenicillin as phenoxymethylpenicillin potassium.

Other ingredients: sodium benzoate (E211), saccharin sodium, trusil orange flavour, orange colour (containing sunset yellow (E110) and ponceau 4R (E124)), sorbitol 60W (E420) and mono ammonium glycyrrhizate.

What Phenoxymethylpenicillin looks like and contents of the pack

Unconstituted powder: An off white to pale pink dry granular powder.

Reconstituted solution: A clear orange solution with an orange odour.

Phenoxymethylpenicillin Oral Solution is available in a size of 100ml on reconstitution.

The product licence holder and manufacturer is:

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Your medicine is distributed by:

*

PL 30464/0070 and PL 30464/0071

This leaflet was last revised October 2015

* Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Retail Syringe - TEVA UK limited, Eastbourne, BN22 9AG.

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland. (not commercialised)

**PACKAGE LEAFLET INFORMATION FOR THE PATIENT LEAFLET –
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**PHENOXYMETHYLPENICILLIN 125MG/5ML AND 250MG/5ML ORAL
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Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you 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

This medicine should not affect your ability to drive or to use machinery.

Important information about some of the ingredients in your medicine**Ponceau 4R (E124) and sunset yellow (E110)**

Can cause allergic type reactions including asthma. Such allergies are common in those people who are allergic to aspirin.

Sorbitol

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8. Replace the cap onto the bottle.

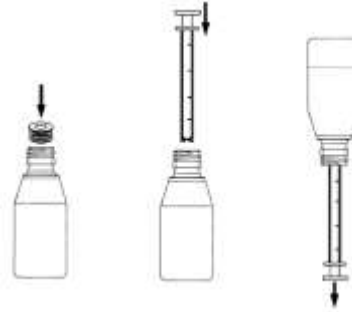


Fig 1

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Fig 3

Administer the dose by introducing the tip of the syringe into the mouth of the infant/child, then apply a light pressure on the plunger to slowly release the solution. Keep it out of the reach of children.

Note: For subsequent dosage follow steps 3 and 4 above, before shaking in order to prevent leakage.

How much of your medicine to take

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For preventing the recurrence of rheumatic fever or chorea:

The usual dose is 250mg twice daily on a continuing basis.

For the prevention of infection in patients without a spleen or patients with sickle cell disease:

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Like all medicines phenoxymethylpenicillin can cause side effects although not everybody gets them.

STOP taking the medicine and tell your doctor IMMEDIATELY if you experience any of the following:

- an allergic reaction - symptoms may include: shortness of breath, skin rash or itching, hives, swelling of the skin (especially of the lips, face or tongue), chills or fever, painful joints
- severe peeling/blistering of the skin
- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema)
- seizures
- profuse watery diarrhoea usually with blood and mucus, stomach pain and fever

Tell your doctor or pharmacist if you notice any of the following and they worry you.

- stomach pain or cramps, nausea (feeling sick), vomiting (being sick) and diarrhoea
- sore mouth
- Hepatitis
- convulsions
- black hairy tongue
- pins and needles or numbness
- sore throats, infections, or fever (may be caused by low white blood cells)
- problems with blood clotting (unusual bleeding or bruising)
- anaemia (may cause lack of energy or tiredness)
- kidney problems, which might cause blood in the urine or reduced amounts of urine
- jaundice – yellowing of skin or whites of the eyes

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, you should contact your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more

information on the safety of this medicine.

5. HOW TO STORE PHENOXYMETHYLPENICILLIN ORAL SOLUTION SUGAR FREE

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Expiry date

Do not use your medicine after the expiry date which is stated on the label. The expiry date, listed as “expiry” on the label, refers to the last day of that month.

Storage conditions

Phenoxymethylpenicillin Oral Solution Sugar Free should be stored for up to 7 days in a refrigerator. Keep it in the pack in which it was given to you. Do not transfer your medicine to another container.

If your doctor tells you to stop your treatment return any left over to the pharmacist. Only keep it if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Phenoxymethylpenicillin Oral Solution Sugar Free contains:

Active ingredient: Each 5ml of oral solution contains 125mg or 250mg of phenoxymethylpenicillin as phenoxymethylpenicillin potassium.

Other ingredients: sodium benzoate (E211), saccharin sodium, trusil orange flavour, orange colour (containing sunset yellow (E110) and ponceau 4R (E124)), sorbitol 60W (E420) and mono ammonium glycyrrhizate.

What Phenoxymethylpenicillin looks like and contents of the pack

Unconstituted powder: An off white to pale pink dry granular powder.

Reconstituted solution: A clear orange solution with an orange odour.

Phenoxymethylpenicillin Oral Solution is available in a size of 100ml on reconstitution.

The product licence holder and manufacturer is:

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Your medicine is distributed by:

*

PL 30464/0070 and PL 30464/0071

This leaflet was last revised October 2015

* Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Retail Syringe - TEVA UK limited, Eastbourne, BN22 9AG.

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland. (not commercialised)