OXYNIC 312.5

(**AMOXICILLIN AND POTASSIUM CLAVULANATE ORAL SUSPENSION BP**)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

What is in this leaflet:

1. WHAT OXYNIC 312.5 ARE AND WHAT THEY ARE USED FOR

Oxynic 312.5 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.

Oxynic 312.5 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 TAKE OXYNIC 312.5

Do not give your child Oxynic 312.5:

• 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 reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.

• if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

→ Do not give Oxynic 312.5 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 Oxynic 312.5.

Warnings and Precautions

Check with their doctor, pharmacist or nurse before giving your child Oxynic 312.5 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 Oxynic 312.5.

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 Oxynic 312.5 or a different medicine.

Conditions you need to look out for
Oxynic 312.5 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 Oxynic 312.5, 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 cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Oxynic 312.5. This is because Oxynic 312.5 can affect the results of these types of tests.

Other medicines and Oxynic 312.5
Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.
If your child is taking allopurinol (used for gout) with Oxynic 312.5, 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 Oxynic 312.5.
If medicines to help stop blood clots (such as warfarin) are taken with Oxynic 312.5 then extra blood tests may be needed.
Oxynic 312.5 can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
Oxynic 312.5 may 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 their doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Oxynic 312.5 can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. HOW TO TAKE OXYNIC 312.5

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 Co-amoxiclav Oral Suspension you should give to your baby or child.

You may be provided with a plastic measuring spoon. You should use this to give the correct dose to your baby or child.

Usual dose – 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three 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 Co-amoxiclav Oral Suspension
• Always shake the bottle well before each dose
• The measuring spoon provided is marked to show doses of
1.25 ml, 2.5 ml and 5 ml. If you are using the measuring spoon, take care to ensure it is filled to the correct dosage marking.
- To measure 1.25 ml of suspension, carefully tilt the spoon and fill up to the dosing line marked 1.25 ml.
- To measure 2.5 ml of suspension, keep the spoon level and fill up to the dosing line marked 2.5 ml.
- To measure 5 ml of suspension, keep the spoon level and fill up to the brim.
Ask your doctor or pharmacist if you are unsure.
• 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 Co-amoxiclav Oral Suspension for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Co-amoxiclav Oral Suspension than you should
If you give your child too much Co-amoxiclav Oral 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 Co-amoxiclav Oral 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 Co-amoxiclav Oral Suspension
Keep giving your child Co-amoxiclav Oral 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.

4. POSSIBLE SIDE EFFECTS

Approximately 5% of patients can be expected to experience adverse reactions. Gastrointestinal disorders with loose stools, nausea and vomiting occur more frequently at higher doses and have been reported more frequently compared to treatment with amoxicillin alone.

Common (>1/100 to <1/10)
Uncommon (>1/1,000 to <1/100)
Rare (>1/10,000 to <1/1,000)
Very rare (<1/10,000)

Infections and infestations
Uncommon
Prolonged and repeated use of the preparation can result in superinfections and colonisation with resistant organisms or yeasts.

<u>Blood and the lymphatic system disorders</u>
Rare
Thrombocystosis, haemolytic anaemia

Very rare
Changes in blood count in form of leucopenia, agranulocytosis, granulocytopenia, thrombocytopenia, pancytopenia, anaemia or myelosuppression and prolongation of the bleeding and prothrombin time have been observed in isolated cases. These manifestations are reversible after discontinuation of therapy.

Immune system disorders

Rare
Typical type I allergic reactions (such as urticaria, purpura), angio-oedema and anaphylaxis can occur less frequently. Erythema multiforme, Lyell syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised erythematous pustulosis, bullous exfoliative dermatitis, serume sickness and vasculitis associated with hypersensitivity rarely occur.
Drug fever.

Psychiatric disorders

Very rare
Hyperactivity, anxiety, sleeplessness, mental confusion and aggression.

Nervous system disorders

Rare
Dizziness, headache and convulsions are rare. Convulsions may occur with impaired renal function or in those receiving high doses.

Gastrointestinal disorders

Common
Gastro-intestinal disturbances such as nausea, vomiting and diarrhoea and pruritis ani have been observed. These side effects are generally of a mild and transitory nature.
Rare
Pseudomembranous colitis, haemorrhagic colitis, mucocutaneous candidiasis, superficial tooth discoloration.
Very rare
Development of a black tongue.
A single study in women with premature rupture of the amnion reported that prophylactic treatment with amoxicillin/clavulanic acid can be associated with an increased risk of necrotising enterocolitis in neonates

Hepato-biliary disorders

Rare
In rare cases a moderate rise in AST and/or ALT values has been reported.
Very rare
Hepatitis and cholestatic jaundice have been reported rarely. Hepatic events occur predominantly in males and elderly patients, particularly those over 60 years of age. The risk of these events occurring increases with treatment for more than 14 days. These side effects are very rarely reported in children. Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until some weeks after treatment has ceased. Hepatic events are usually transient. However they may be severe and in very rare cases a fatal outcome has been reported. These have mostly occurred in patients with a serious underlying disease, or patients taking potentially hepatotoxic agents in addition to amoxicillin/clavulanic acid.

Skin and subcutaneous tissue disorders

Common
Allergic skin reactions occur significantly more often than with other penicillins and generally are maculopapular in nature. In some cases ‘fifth day rash’ (a morbilliform exanthema) is reported. This is dependent on the size of the dose and the patient’s condition.

Renal and urinary disorders

Very rare
Interstitial nephritis has occurred on a single occasion. Crystalluria has been reported.

Reproductive system and breast disorders
Uncommon
Vaginal itching and discharge.

5. How to store Oxynic 312.5

Keep this medicine out of the sight and reach of children.

Dry powder Store in the original package in order to protect from moisture. Do not store above 30°C.

Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.

Liquid suspension Store in a refrigerator (2°C - 8°C). Do not freeze.
Once made up, the suspension should be used within 7 days.

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 you to protect the environment

6. Further information

What Oxynic 312.5 contains:

Sr. No.	**Excipients**	**Specification**
1	Colloidal anhydrous silica	BP
2	Hypromellose	
3	Xanthan Gum	BP
4	Aspartame	BP
5	Citric acid anhydrous	BP
6	Sodium benzoate	BP
7	Silicon Dioxide	USP
8	Essence dry Mango	IH

Marketing authorization holder

Company Name : GB PHARMA LIMITED
Address : 65 Chatsworth Road, London NW2 4BG
Country : United Kingdom
Phone : +44 (0)2088301057
Fax : + 44 (0) 2088304807
E-mail : info@gbpharma.co.uk