PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

(OXYNIC INJECTION) Amoxicillin and Potassium Clavulanate injection BP (600/1.2)
(Amoxicillin/Clavulanic acid)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider or pharmacist.

In this leaflet:

1. WHAT OXYNIC INJECTION IS AND WHAT IT IS USED FOR

Oxynic injection 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 injection is used to treat the following infections:

Upper Respiratory Tract Infections (including ENT): e.g. tonsillitis, sinusitis, otitis media

Lower Respiratory Tract Infections: e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia

Genito-urinary Tract Infections: e.g. cystitis, urethritis, pyelonephritis, female genital infection Skin and Soft Tissue Infections, Bone and Joint Infections (e.g. osteomyelitis)

Other Infections: e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis, septicaemia, peritonitis, postsurgical infections. Also, indicated for prophylaxis against infection associated with major surgical procedures such as GI, pelvic, head and neck, cardiac, renal, joint replacement and biliary tract surgery. Infections caused by amoxicillin susceptible organisms are amenable to Oxynic injection treatment due to its amoxicillin content. Mixed infections caused by amoxicillin susceptible organism in conjunction with Amoxicillin & Clavulanate -susceptible β-lactamase-producing organisms.

2. BEFORE YOU USE OXYNIC INJECTION

Do not oxynic injection

- If you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of oxynic injection.

- If you have ever had a severe allergic reaction to any other antibiotic. This can include a
- skin rash or swelling of the face or neck
- If you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not take Oxynic injection if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before having Oxynic injection.

Take special care with oxynic injection

Warnings and Precautions
Talk to your doctor, pharmacist or nurse before having this medicine if you:
• 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 you, talk to your doctor, pharmacist or nurse before taking oxynic injection.
In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of oxynic injection or a different medicine.

Conditions you need to look out for
Oxynic injection can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking oxynic injection, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Using other medicines
Please tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This includes medicines that can be bought without a prescription and herbal medicines. If you are taking allopurinol (used for gout) with oxynic injection, it may be more likely that youwill have an allergic skin reaction. If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of oxynic injection.
If medicines to help stop blood clots (such as warfarin) are taken with oxynic injection then extra blood tests may be needed. oxynic injection can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. oxynic injection can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.
If you are a transplant patient taking mycophenolate mofetil talk to your doctor.

Using oxynic injection with food and drink
Blood and urine tests
If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Oxynic injection. This is because Oxynic injection can affect the results of these types of tests.

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, pharmacist or nurse for advice before taking this medicine.

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

Important information about some of the ingredients of oxynic injection
Oxynic injection contains sodium and potassium:
500 mg/100 mg powder for injection or infusion. Oxynic injection 500 mg/100 mg contains approximately 31.4 mg (1.4 mmol) of sodium and 19.6 mg (0.5 mmol) of potassium. This should be considered if you are on a controlled sodium diet.

1000 mg/200 mg powder for injection or infusion
Oxynic injection 1000 mg/200 mg contains approximately 62.9 mg (2.7 mmol) of sodium and 39.3 mg (1.0 mmol) of potassium. This should be considered by patients with kidney problems or patients on a controlled potassium diet.

3. HOW TO USE OXYNIC INJECTION
Always oxynic injection exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.
The usual recommended doses are: 500 mg/100 mg, 1000 mg/200 mg powder for injection or infusion. Posology and Method of Administration oxynic Injection is for intravenous use.
Dosage:
Children 0-3 months: 30mg/kg* oxynic Injection every 12 hours in infants < 4kg and 30mg/kg* oxynic Injection every 8 hours in infants >4kg
Children 3 months - 12 years: Usually 30mg/kg* oxynic Injection 8 hourly. In more serious infections, increase frequency to 6 hourly intervals.
Adults and Children 40kg and over: Usually 1.2 g/8 hourly. In more serious infections, increase frequency to 6 hourly intervals.
*Each 30mg oxynic Injection provides 5mg clavulanic acid with 25 mg amoxicillin.
Dosage for surgical prophylaxis:
Surgical prophylaxis with oxynic Injection should aim to protect the patient for the period of risk of infection. Accordingly, procedures in adults lasting for less than 1 hour are successfully covered by 1.2g oxynic Injection Intravenous given at induction of anaesthesia. Longer operations require subsequent doses of 1.2g oxynic Injection IV (up to 4 doses in 24 hours), and this regime can be

continued for several days if the procedure has significantly increased the risk of infection. Clear clinical signs of infection at operation will require a normal course of IV oxynic therapy post-operatively.

Dosage in renal impairment:
Adults: Dosing adjustments are based on the maximum recommended level of amoxicillin.

Route of Administration	Mild Impairment (creatinine clearance >30mL/min)	Moderate Impairment (creatinine clearance 10-30mL/min)	Severe Impairment (creatinine clearance <10mL/min)
Intravenous	No change in dosage	1.2g IV stat followed by 600mg IV 12 hourly	1.2g IV stat followed by 600mg IV 24 hourly. Dialysis decreases serum concentrations of oxynic. An additional 600mg IV dose may need to be supplemented at the end of dialysis

Each 1.2g vial of oxynic Injection contains 1.0mmoL of potassium and 3.1mmoL of sodium (approx.).
Children: Dosing adjustments are based on the maximum recommended level of amoxicillin.

Route of Administration	Mild Impairment (creatinine clearance >30mL/min)	Moderate Impairment (creatinine clearance 10-30mL/min)	Severe Impairment (creatinine clearance <10mL/min)
Intravenous	No change in dosage	30 mg/kg 12 hourly	30 mg/kg every 24 hours. Dialysis decreases serum concentrations of oxynic Injection. additional 15 mg/kg may be supplemented al the end of dialysis, then 30 mg/kg/day.

Dosage in hepatic impairment:
Dose with caution; monitor hepatic function at regular intervals for both adults and children.
Dosage in elderly:
No adjustment needed, dose as for adults. If there is evidence of renal impairment, dose should be adjusted as for renally impaired adults.
Use in children: Dosing adjustments are based on the maximum recommended level of amoxicillin.

How oxynic injection will be given to you
It may be administered either by intravenous injection or by intermittent infusion It is not suitable for intramuscular administration.

600 mg Vial -To reconstitute dissolve in 10 ml of Sterile Water for Injections.
1.2 g Vial -To reconstitute dissolve in 20 ml of Sterile Water for Injections.
Reconstituted solution should not be frozen. oxynic Injection intravenous solutions should be used immediately after reconstitution.
Intravenous Injection: The stability of oxynic Injection intravenous solution is concentration dependent, thus oxynic Injection intravenous should be used immediately upon reconstitution and given by slow intravenous injection over a period of 3-4 minutes, oxynic Injection may be injected directly in to a vein or via tube.
Intravenous Infusion: Alternatively, oxynic Injection intravenous may be infused in Water for Injection or Sodium Chloride Intravenous Injection (0.9% w/v). Add, without delay 600 mg reconstituted solution to 50 ml infusion fluid. Infuse over 30-40 minutes and complete within four hours of reconstitution. Other appropriate infusion fluids includes Compound Sodium Chloride Intravenous Infusion, Compound Sodium Lactate Intravenous Infusion (Ringer Lactate Solution, Hartmann's Solution), Potassium Chloride and Sodium Chloride Intravenous Infusion.
Oxynic Injection is less stable in infusion containing glucose, dextran or bicarbonate. Reconstituted solution of oxynic Injection should therefore not be added to such infusions but may be injected into the drip tubing over a period of 3-4 minutes.
Any residual antibiotic solutions should be discarded.
Therapy can be started parenterally and continued with an oral preparation. Treatment should not be extended beyond 14 days without review.

If you more oxynic injection than you should
It is unlikely you will be given too much, but if you think you have been given too much oxynic injection, tell your doctor, pharmacist or nurse immediately. Signs may be an upset stomach (feeling sick, being sick or diarrhoea) or convulsions.
If you have any further questions about how this product is given, ask your doctor, pharmacist or nurse.

If you forget to oxynic injection
Do not take a double dose to make up for a forgotten injection dose.

If you stop using oxynic injection
If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.
Like all medicines, oxynic injection can cause side effects, although not everybody gets them.
Clostridium difficile-associated diarrhoea and colitis (antibiotic-associated pseudo-membranous colitis) caused by toxin producing clostridia has been reported. Adverse reactions observed in

paediatric patients are similar to those reported in adults. Rarely, in <1% of patients, dizziness, headache, rash, urticaria, nausea, vomiting, diarrhoea, vaginitis, fever and slight thrombocytosis have been observed.
Moderate increases in serum concentrations of AST (SGOT) and/or ALT (SGPT), alkaline phosphatase and/or bilirubin have been observed. Hepatic dysfunction reflected as cholestatic, hepatocellular or mixed cholestatic hepatocellular changes have been reported most frequently in geriatric patients, males, or in patients receiving long-term therapy.

5. HOW TO STORE OXYNIC INJECTION

Keep this medicine out of the sight and reach of children.
Store at temperature not exceeding 30°C. Protect from light & moisture.
Do not use this medicine after the expiry date which is stated on the carton. 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. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

What oxynic injection contains

- The active substances are amoxicillin (a penicillin) and clavulanic acid.
- There are no other ingredients

What oxynic injection looks like and contents of the pack Supplier and Manufacturer
Powder for injection filled in labeled glass vial. Such a vial packed in carton with package insert.

- What oxynic injection looks like and contents of the combipacks.
- Oxynic injection is available in two strengths, 500/100 mg and 1000/200mg, and is available in combipacks.
- Oxynic injection 500/100mg vials each contain 500 mg of amoxicillin (as sodium salt) with
- 100mg of clavulanic acid (as potassium salt).
- Oxynic injection 1000/200mg vials each contain 1000 mg of amoxicillin (as sodium salt) with 200mg of clavulanic acid (as potassium salt).

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