

- tead all of this leaflet carefully before you start king this medicine.

  Keep this leaflet. You may need to read it again.

  If you have any further questions, sak your doctor or pharmacist.

  This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if the 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, pleast tell your doctor or pharmacist.

- In this leaflet:

  1. WHAT IS CIPROMAX AND WHAT IT IS USED FOR 2. BEFORE YOU TAKE CIPROMAX

  3. HOW TO TAKE CIPROMAX

  4. POSSIBLE SIDE EFFECTS

  5. HOW TO STORE CIPROMAX

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FURTHER INFORMATION

1. WHAT IS CIPROMAX AND WHAT IT IS USED FOR
(ipromax belongs to a group of ratificities known as quinclones. It has high anti-bacterial activity.
(ipromaxworks by killing bacteria that cause infections. It onlyworks against specific strains of bacter
Adults:

(ipromax is used to treat the following bacterial infections:

1. respiratory treal infections (a.e. certain types of preumonia)

1. long lasting or recurring ear or sirus infections

1. uninary tract infections (bladet and kidneys infection)

1. infections of the testicios

1. genital organ infections in women(e.g. gonorrhoea, a sexually transmitted disease)

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1. genital organ infections in six women(e.g. genorrhoea, and infections)

1. bone and joint infections

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1. bone and joint infections in patients with a very low white blood cell count (neutropenia)

1. to prevent infections due to the bacteria Neisseria meningities which causes meningities (prain in spiritud cord infarmation)

1. anthrax inhalation exposure (infection that occurs when the spores from bacteria Bacillus anthrax enters the body).

1. (Gipromax may be used in the management of patients with ow white blood cell counts (neutroper (approximate the body).

anthrax inhalation exposure (infection that occurs when the spores from bacteria Bacillus anthracis enters the body).

Cipromax may be used in the management of patients with low white blood cell counts (neutropenia) who have a fever that is suspected to be due to a bacterial infection. If you have a sever lentice or one that is caused by more than one type of bacteria, you may be given additional antibiotic treatment in addition to Cipromax.

Children and adolescents:

Cipromax should be used under specialist medical supervision, to treat the following bacterial infections for children and adolescents:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis (genetic disorder known to be an inherited disease of the secretory glands, including he glands that make mucus and sweet).

- complicated urinary tract infections, including infections that have reached the kidneys (pyelorephris).

- antirax inhalation exposure (infection that occurs when the spores from bacteria Bacillus antiracis enters the body).

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 Cipromax may also be used to treat other specific severe infections in children and adolesc your doctor considers this as necessary.

- enters the body).

  Cipromax may also be used to treat other specific severe infections in children and adolescents when your doctor considers this as necessary.

  2. BEFORE YOU TAKE CIPROMAX

  Do not take Cipromax Ifyou:

  are altergic (hypersensitive) to the Ciprofloxacin, to any other quincione drugs or to any of the other ingredients of Cipromax bablets (see section 6).

  are taking tizandine (see Section 2: Taking other medicines). Takes special care with Cipromax Tablets.

  Before taking Cipromax Tablets, tell your doctor If:

  You suffer from filts or epilesy or any other neurological conditions.

  You have ever had kidney problems because your treatment may need to be adjusted.

  You have ever had kidney problems during previous treatment with antibiotics such as Cipromax. Stop taking Cipromax immediately and get medical help right away.

  You have an instery of lendor problems during previous treatment with antibiotics such as Cipromax. You have a history of some problems during previous treatment with antibiotics such as Cipromax. You have any system of the problems of the properties of the properties.

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  Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged off peripheral neoproperties.

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  Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged OT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'tradycardial'), have a weak heart (heart fallure), have a history of heart attack (myocardial infarcion), you are female or elderly or you are taking other medicines.

  Caution should be taken when using th

- You may experience symptoms of neuropathy such as pain, burning, lingling, numbness and/or weakness. If this happens, slot paking Cipromax tablets and contact your doctor immediately. \*All antibacterial fluoroquinolone drugs taken by mouth or by injection can cause permanent nerve damage.
   Diarrhose may develop while you are taking antibiotics, including Cipromax tablets, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking Cipromax tablets immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor. I rell the doctor or laboratory staff that you are taking Cipromax tablets if you have to provide a blood or urine sample.
   If you suffer from kidney problems, tell the doctor because your dose may need to be adjusted.
   Cipromax tablets may cause eliver damage. If you notice any symptoms such as loss of appetite, jaundice yellowing of the skin), dark urine, litching, or tendemess of the stomach, alop taking Cipromax tablets and contact your doctor immediately.
  Cipromax tablets may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general contilion, or fever with local infection symptoms such as fever and serious to check possible reduction of white blood cells (aganalocyloss). It is important to inferor your doctor about your medicine.
  Tell your doctor if you or a member of your family is known to have a deficiency in glucose-6-

presymbotion of unitary proclaims you include see your doctor interelosary. A block less win de sixen to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

Tell your doctor if your a member of your family is known to have a deficiency in glucose-6-phosphias deliy/organes (GRPD), since you may experience a risk of anemia with Copromax habits. Avoid exposure to strong sunlight, or artificial UV light with a lating Cipromax babits. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Taking other medicines a sunlight, or artificial UV light such as sunbeds.

Taking other medicines obtained without a prescription.

You must let your doctor or pharmacel if you are taking or have recently taken any other medicines, including those medicines obtained without a prescription.

You must let your doctor if you are taking or have recently taken any other medicines that belong to the group of anti-arrhythmics (e.g., quinidine, hydroquinidine, disopyramide, amiodarone, sotalo,, dofetilies, builties), tricyclic antidepressants, some antimicrobials (that belong to the group of macroides), some antipsychotics.

Do not take Cipromax together with tizandidine, because this may cause side effects such as low blood pressure and skepiness (see Section 2: 'Do not take Cipromax').

The following medicines are known to interact with Cipromax in your body, Taking Cipromax together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experimenia side effects.

Tell your doctor if you are taking:

any druge which thin the blood (rown as anti-coagulants e.g. warfarin)

cyclosporin (used to treat pointages)

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cyclosporin (used to treat pointages)

methorizexate (for cartain types of cancer, psoriasis, rheumatoid arthritis and in organ transplantation)

eiglibenciamide (used to treat nausea and vomiting (feeling/

- other medicines that can after your heart rhythm: medicines that belong to the group of anti-other medicines that can after your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amidoznoe, sotalol, dofellide, ibuillido), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolidos), some

# Introyclic antidepressants, some antimercolosis (una usering units production antipsycholics. Spromax may increase the levels of the following medicines in your bloopentoxilyline (for circulatory disorders) caffeine duloxetine (for depression, disbetic nerve damage or incontinence) lidocaine (for heart conditions or anesthetic use)

- lidocaine (for heart conditions or anesthetic use) sidenafil (e.g. for eractile dysfunction) ome medicines reduce the effect of Cipromax. Tell your doctor if you take or w antacids omeprazion imineral supplements su

- ric phosphate binder (e.g. sevelamer)
- meacines or supplements containing caclium, magnesium, aluminium or iron (e.g. didanosine tablets (an antiviral drug used to treat HIV))
  If these medicines are essential, take Cipromax about two hours before or no sooner than four hours after them.
  Taking Cipromax with food and drink

after them.

Taking Cipromax with food and drink

Unless you take Cipromax during meals, do not eat or drink any dairy products (e.g. milk or yogurt) or drinks with added calcium. These can affect the absorption of cipromax and so you should take your tablets either 1 to 2 hours before or at least 4 hours after you have such products.

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Pregnancy and breast-feeding.

It is preferable to avoid the use of Cipromax during pregnancy. Tell your doctor if you are pregnant or planning to become pregnant.

Do not take Cipromax tablets during breast feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Ask your doctor of pharmadist for advice before taking any other medicine.

Driving and using machines

Cipromax may make you feel less afert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Cipromax before driving a vehicle or operating machinery. If in doubt, tak to sure decide.

## 3. HOW TO TAKE CIPROMAX TABLETS

3. HOW TO TAKE CIPROMAX TABLETS Always take Cipromax tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets should always be taken with plenty of water, as this will help to prevent the formation of tiny crystals in your urine (crystalluria). You can take the tablets at meal times or between meals. Any calcium you take as a part of a meal will not seriously affect uptake. However, do not take cipromax tablets with dairy products such as milk or yogurt or with fortified fruitjuices (eg. Calcium-fortified orange juice). Tell your doctor if you suffer from kitchey problems because your dose may need to be adjusted. Your dose will be dependent on the type and severity of your infection, your age, weight and kidney function.

Adults
The usual adult dose is between 100 – 750mg twice daily. In Respiratory infections the usual dose is 500mg-750mg twice daily. In Infections of the bladder and kidneys, the usual dose is 250 - 500mg twice daily. In gonormose, the usual dose is 250 - 500mg bax easily. In gonormose, the usual dose is 250 - 500mg twice daily. In gonormose, the usual dose is 500 mg twice daily. In intra-abdominal infections, skin and soft tissue infections, because the usual dose is 500 mg twice daily. In infections due to Bacterium Nesseria meninglidist the usual dose is 500-750mg twice daily. In infections due to Bacterium Nesseria meninglidist the usual dose is 500mg as a single dose. Inhalation anthrax exposure the usual dose is 500mg twice daily.

returns

to will decide what dose to give you. This may be lower than the usual adult dose depo everity of your infection and your kidney function.

Kidney/Liver problems
Your doctor will decide what dose to give you depending on your kidney and liver function. Special dosting instructions are needed if you are on haemodialysis or having continuous perinoneal dialysis).
Children and adolescents
The use of Cipromax Tablets is not generally recommended in children. However in some cases treatment with these tablets is of benefit and your doctor may decide to treat your child with this drug particularly for the below mentioned infections.

- Cystic fibrosis the usual dose is 20mg/kg body weight twice daily with a maximum daily dose of 750 mg.

- Ogsitu natuse the used to be a considered of the considered of the

• Other severe infections the usual dose is 20mg f/sg body weight twice daily with a maximum of 750mg per dose. Do not skip any doses of Cipromax, or stop taking it, even if you begin to feel better, until you finish your prescribed treatment unless:
• You have nerve problems. See '2. BEFORE YOU TAKE CIPROMAX'
• You have nerve problems. See '2. BEFORE YOU TAKE CIPROMAX'
1 to very important that you follow your doctor's instructions as to how many Cipromax Tablets to take, how often to take them and for how long you should continue to take your ablets. The normal duration of treatment is between 5 to 21 days (although this may be longer), depending on the type and severity or infection.

of intection. If you take more Cipromax tablets than you should if you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacted or hospital emergency department immediately. Always take any tablets left over with you, also the box and teeflet as this will allow easier identification of the tablets.

Always take any lablets iet over well you, and the lablets. If you forget to take Cloromax tablets. If you forget to take Cloromax tablets. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take in missed dose and just carry on as before. Do not take a double dose to make up for a forgotant node. Be sure to complete your course of treatment.

If you stop taking Cloromax tablets. It is important that you finish the course of treatment even if you begin to feel better after a few days. If you stop taking this medicine too soon your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to the antiblotic. If you have any further questions on the use of this product, sak your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

4. POSSIBLE SIDE EFFECTS
Libral amedicines, Cipromax can cause side-effects, although not everybody gets them.
About 5 - 14% of patients have side-effects and the most common side-effects involve the gut and the nervous system.
If any of the following symptoms occur soon after taking your tablets, stop taking the tablets and tell your doctor immediately. This kind of reaction is rare and may mean you are suffering from an altergic reaction to the medicine:
- Rash, fliching, a lumpy sidn rash ('hlves'), fever, small red spots on the body, increased sensitivity to sunlight or very rarely severe skin reactions such as large fluid filled blisters, peeling, sores and ulceration. Ulceration can also occur in the mouth and throat, around the anus and genital region and on the surface of the exist.

- ulceration. Ulceration can also occur in the mouth and throat, around the anus and gential region and on the surface of the eyes sudden wheeziness or tightness of the chest Swelling of the eyelids, face, lips or blood vessels in the skin Skichess and headache (su should also tell your doctor immediately and stop taking your tablets if you notice: Pain or inflammation in the tendons. This effect occurs in isolated cases. If these symptoms are experienced you should stop taking your tablet, rest the affected limb and consult your doctor immediately. Severe diarrhoea with bleeding or mucus. This effect occurs in less than one in a thousand people. A feeling that you want to physically harm yourself. This only occurs in solated cases. Changes in sensation and never damage (Peripheral Neuropathy that may be irreversible) damage to the nerves in arms, hands, legs, or feet can happen in people taking fluoroquinolones, includingcipro.

  Ther possible side-effects, which may occur, are listed below:

  Common aids effects (between 1 and 10 in every 100 people are likely to get these):

  nauses, diarrhoea

- Inflammation of the water or the discourvessers versionary.

  pancreatitis
   small, bleeding under the skin (peterbiae); various skin eruptions or rashes (for example, the
  potentially flatal Stevens-Lohnson syndrome or toxic epidermal necrolysis)
   muscle weakness, tendon inflammation, tendon rupture especially of the large tendon at the back
  of the ankle (Achilles tendon) (see Section 2: Take special care with Cipromax); worsening of the
  symptoms of myasthenia gravis (see Section 2: Take special care with Cipromax)
  Frequency not known (cannot be estimated from the available data)
   troubles associated with the nervous system such as pain, buming, lingling, numbness and/or
  weakness in extremities
- troubles associated with the nervous system such as pain, ourning, unging, numoness andor weakness in extremillies abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (alted 'prolongation of QT interval', seen on ECG, electrical activity of the heart) pustular rash

- Dissular tear or blood clotting (in patients treated with Vitamin K antagonists)
   If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Slore below 30°C.

Keep out of the reach and sight of children.

Do not use your tablets after the expiry date stated on carton.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

dispose of medicines no longer required. These measures will neip to protect the environment.

6. FURTHER INFORMATION
What Cipromax tablet contains
The active ingredient:
Cipromax 250 ing film-costed tablets: Each Film-costed tablet contains Ciprofloxacin Hydrochloride
Monohydrate equivalent to 250 mg. Ciprofloxacin as an active ingredient
Cipromax 500 ing film-costed tablets: Each Film-costed tablet contains Ciprofloxacin Hydrochloride
Monohydrate equivalent to 500 mg. Ciprofloxacin as an active ingredient
Cipromax 750 ing film-costed tablets: Each Film-costed tablet contains Ciprofloxacin Hydrochloride
Monohydrate equivalent to 750 mg. Ciprofloxacin as an active ingredient
The Other Ingredients are:
Tablet Core: Ciprofloxacin Hydrochloride, Avicel PH 101, Sodium Starch Glycolate, Povidone K-30,
Colloidal Silicon Dicikide and Megnesium Stearate.
Tablet Cost:
Cipromax 250 mg film-costed tablets:
Polyethyeine Glycol MW 5000, Polyeorbate 80, Titanium Dicxide, Purified Talc and Hydroxypropyl
Methylcolatiosa.

- Cipromax 500 mg film-costed tablets

Polyethylene Glycol MW 6000, Polysorbate 80, Titanium Dioxide, Purified Talc and Hydroxypropyl Methylciatiluse.

- Cipromax 500mg film-coated tablets
- Cipromax 500mg film-coated tablets
- Cipromax 250 mg film-coated tablets
- Polyethylene (Sycol MW 6000, Polysorbate 80, Titanium Dioxide, Purified Talc and Hydroxypropyl Methylciatiluse.

What Cipromax 250 mg film-coated tablets: A white to rif-white round, biconvex film-coated tablet engraved with SP 149° on one side and breashing on the other side. Each unit carton contains 10 film-coated Capromax 500 mg film-coated tablets: A light blue obting, biconvex film-coated tablet engraved with SP 149° on one side and breakline on the other side. Each unit carton contains 10 film-coated tablet in one bilister strip.

Cipromax 500 mg film-coated tablets: A white to film-white obting, biconvex film-coated tablet engraved with SP 127° on one side and breakline on the other side. Each unit carton contains 10 film-coated tablets with SP 127° on one side and breakline on the other side. Each unit carton contains 10 film-coated tablets in one bilister strip.

Contents of the pack.

- - contents of the pack

    Cipromax 250 mg film-coated tablets & Cipromax 500 mg film-coated tablets & Cipromax 500 mg film-coated tablets & Cipromax 500 mg film-coated tablets. Not all pack s
- Pack sizes of 10, 100 and 1000 film-c
   Cipromax 750 mg film-coated tablets:
   Are available in blister packs.
   Pack sizes of 10 film-coated tablets.

A medicament is a product which affects your hearin, amune consumption instructions is dangerous for you.

Follow shirdly the doctor's prescription, the method of use and the instructions pharmacists who sold the medicament.

The doctor and the pharmacists are experts in medicine, its benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you.

Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Minist Union of Arab Pharmacists

