

CIPROFLOXACIN ALPHAPHARM

ciprofloxacin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CIPROFLOXACIN ALPHAPHARM. It does not contain all the available information. It does not take the place of talking to your doctor or your pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CIPROFLOXACIN ALPHAPHARM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CIPROFLOXACIN ALPHAPHARM is used for

CIPROFLOXACIN ALPHAPHARM is used to treat serious infections in the lungs, skin, blood, bone and joints, kidneys and bowel.

CIPROFLOXACIN ALPHAPHARM is also used to treat inhalational anthrax (an infection caused by breathing in the spores of bacteria).

CIPROFLOXACIN ALPHAPHARM contains the drug ciprofloxacin, which is an antibiotic belonging to a group of medicines called quinolones (pronounced kwin-o-lones). These antibiotics work by killing the bacteria which cause infections in the body.

CIPROFLOXACIN ALPHAPHARM is used in hospitalised patients where the use of ciprofloxacin tablets is inappropriate.

CIPROFLOXACIN ALPHAPHARM will not work against infections caused by viruses such as colds or the flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you are given CIPROFLOXACIN ALPHAPHARM

When you must not be given it

You must not be given CIPROFLOXACIN ALPHAPHARM if you have an allergy to:

- ciprofloxacin
- other quinolone antibiotics including nalidixic acid, moxifloxacin, norfloxacin
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not be given CIPROFLOXACIN ALPHAPHARM if you are also taking a medicine called tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis or injury or diseases of the spinal cord.

CIPROFLOXACIN ALPHAPHARM can interfere with tizanidine and can lead to undesirable side effects.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, inform your doctor.

The contents of the infusion bag are not to be used if it is cloudy or has little specks in it.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

CIPROFLOXACIN ALPHAPHARM is not recommended if you are pregnant. Medicines similar to CIPROFLOXACIN ALPHAPHARM have caused joint disease in immature animals.

Your doctor will discuss the risks and benefits with you of taking this medicine during pregnancy.

Tell your doctor if you are breastfeeding.

CIPROFLOXACIN ALPHAPHARM passes into breast milk. Your doctor will tell you whether you should be given it or temporarily stop breastfeeding while you are receiving CIPROFLOXACIN ALPHAPHARM.

CIPROFLOXACIN ALPHAPHARM is not recommended in children under 18 years of age except for use in inhalational anthrax.

CIPROFLOXACIN ALPHAPHARM should be used with caution in elderly patients as they are more prone to side effects.

Tell your doctor if you have or have had any of the following medical conditions:

- epilepsy, fits, seizures or convulsions
- stroke
- kidney disease
- liver disease
- arrhythmias (fast or irregular heartbeats).
CIPROFLOXACIN ALPHAPHARM may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels
- conditions where you have taken corticosteroids. You may be at increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes restricted movement
- myasthenia gravis, a condition where the muscles become weak. CIPROFLOXACIN ALPHAPHARM can worsen the symptoms of this condition.

- a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)
- have or have had a mental illness
- have diabetes

If you have not told your doctor about any of the above, tell them before you are given CIPROFLOXACIN ALPHAPHARM.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by CIPROFLOXACIN ALPHAPHARM. These include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- oral anticoagulants, medicines used to prevent blood clots such as warfarin and its derivatives
- phenytoin, a medicine used to treat epilepsy
- oral antidiabetic agents

- ciclosporin, a medicine used to suppress the immune system
- NSAIDs (non-steroidal anti-inflammatory drugs), used to treat pain, arthritis and other inflammatory conditions
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis or severe rheumatoid arthritis
- duloxetine, a medicine used to treat depression, anxiety and nerve pain in people with diabetes
- clozapine, a medicine used to treat schizophrenia
- ropinirole, a medicine used to treat Parkinson's disease or restless legs syndrome
- lidocaine (lignocaine), a local anaesthetic medicine used to numb pain or cause loss of sensation
- pentoxifylline (oxpentifylline), a medicine used to treat circulation disorders
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine used to treat sleep disorders

These medicines

These medicines may be affected by CIPROFLOXACIN ALPHAPHARM or may affect how well it works.

You may need different amounts of your medicine, or you may need to take different medicines.

Some medicines may interfere with CIPROFLOXACIN ALPHAPHARM. These include:

- probenecid, a medicine used to treat gout
- omeprazole, a medicine used to treat stomach ulcers and other conditions where the stomach produces too much acid

You can still take these medicines while you are receiving CIPROFLOXACIN ALPHAPHARM.

However, you must be given CIPROFLOXACIN ALPHAPHARM at least 2 hours before or 2 hours after taking any of these medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while receiving this medicine.

How CIPROFLOXACIN ALPHAPHARM is given

CIPROFLOXACIN ALPHAPHARM is given as a slow injection into a vein, usually as a drip, over a period of 60 minutes, by a doctor or a nurse.

CIPROFLOXACIN ALPHAPHARM is incompatible with alkaline drugs.

How much to receive

This depends on your condition, and will be decided by your doctor.

The usual adult dose is 200-300 mg twice a day for one to two weeks. Normally your doctor will put you on antibiotic tablets as soon as possible; but for difficult infections longer intravenous therapy may be required.

If you have not been given your next dose, tell the doctor or nurse on duty as soon as possible.

If you are given too much (overdose)

Immediately tell your doctor or nurse on duty or telephone the Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have received too much CIPROFLOXACIN ALPHAPHARM. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are receiving CIPROFLOXACIN ALPHAPHARM

Things you must do

If you are about to be started on any new medicine, remind your doctor that you are receiving CIPROFLOXACIN ALPHAPHARM.

Tell any other doctors, dentists, nurses and pharmacists who are treating you that you are receiving CIPROFLOXACIN ALPHAPHARM.

If you are going to have surgery, tell your doctor, surgeon or anaesthetist that you are receiving CIPROFLOXACIN ALPHAPHARM.

The use of CIPROFLOXACIN ALPHAPHARM may affect the results of certain laboratory tests.

If you are about to have any tests, tell your doctor that you are receiving this medicine.

Drink plenty of water while you are receiving CIPROFLOXACIN ALPHAPHARM.

This helps to stop crystals forming in your urine.

If you become pregnant while you are receiving CIPROFLOXACIN ALPHAPHARM, tell your doctor immediately.

If you develop diarrhoea, tell your doctor, nurse or pharmacist immediately.

Do this even if it occurs several weeks after you have stopped receiving CIPROFLOXACIN ALPHAPHARM.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Do not take any medicines for diarrhoea without first checking with your doctor, nurse or pharmacist.

Tell your doctor immediately if you experience symptoms of depression or self-endangering behaviour.

CIPROFLOXACIN ALPHAPHARM should be discontinued immediately.

Tell your doctor immediately if you develop pain, burning, tingling, numbness or weakness in any part of your body.

CIPROFLOXACIN ALPHAPHARM should be discontinued immediately.

Things you must not do

Do not receive CIPROFLOXACIN ALPHAPHARM to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using CIPROFLOXACIN ALPHAPHARM because you are feeling better, unless your doctor told you to do so.

If you do not complete the full course prescribed by your doctor, some of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear up completely or it may return.

What to be careful of

Avoid excessive exposure to direct sunlight.

Your skin may become more prone to sunburn. If such a reaction occurs, tell your doctor.

Be careful driving or operating machinery until you know how CIPROFLOXACIN ALPHAPHARM affects you.

CIPROFLOXACIN ALPHAPHARM may cause dizziness in some patients, especially after the first few doses. Your ability to drive and/or operate machinery may be impaired. If you drink alcohol while using this medicine, dizziness may be worse.

CIPROFLOXACIN ALPHAPHARM may increase the stimulating effect of caffeine.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving CIPROFLOXACIN ALPHAPHARM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

CIPROFLOXACIN ALPHAPHARM is usually well tolerated.

CIPROFLOXACIN ALPHAPHARM can cause redness, pain, oedema, hypersensitivity and inflammation at the injection site.

Vomiting and rash were common in patients switching from ciprofloxacin infusion to ciprofloxacin tablets.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or nurse to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea
- diarrhoea

These are the common side effects of CIPROFLOXACIN ALPHAPHARM. They are usually mild and short-lived.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- severe skin rashes, peeling of the skin and/or mucosal reactions
- signs of allergy such as rash, swelling of the face, lips, mouth or throat or other parts of the body, shortness of breath, wheezing or difficulty in breathing

- fainting
- yellowing of the skin and eyes, also called jaundice
- severe watery or bloody diarrhoea, even if it occurs several weeks after receiving CIPROFLOXACIN ALPHAPHARM
- fits (seizures, convulsions)
- confusion, nightmares, hallucinations and psychotic reaction (even progressing to self-endangering behaviour)
- fast or irregular heart beats
- visual disturbances (eye problems)
- ringing in the ear, loss of hearing
- abdominal pain/cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue
- pain, burning, tingling, numbness and/or weakness in your limbs

These serious side effects are rare. If you have any of them, you may need urgent medical attention.

In isolated instances, some serious side effects may be long-lasting (> 30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbance of senses.

Photosensitivity (getting sunburnt very easily) can occasionally occur with ciprofloxacin. However, it is

temporary and staying out of direct sunlight while receiving CIPROFLOXACIN ALPHAPHARM will prevent it from happening.

Rarely, there can be a worsening of the symptoms of myasthenia gravis. This is a condition in which the muscles become weak and tire easily, causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs.

Rarely, the Achilles tendon (extending from the calf in the leg to the heel of the foot) or other tendons have been torn after CIPROFLOXACIN ALPHAPHARM therapy. This may occur even within the first 48 hours of treatment and up to several months after completing treatment with CIPROFLOXACIN ALPHAPHARM. This risk of tendon damage may be increased in elderly patients, during strenuous physical activity, if you are currently being treated with a type of medicine called corticosteroids, if you have reduced kidney function or have received solid organ transplants.

Tell your doctor immediately if you feel any discomfort, pain or inflammation of a tendon.

Rarely, you may experience hyperglycaemia (high blood sugar) or hypoglycaemia (low blood sugar). Symptoms of hyperglycaemia include increased thirst, appetite and urination. Symptoms of hypoglycaemia include weakness, shaking, sweating, light headedness, headache, behavioural changes, confusion, numbness/pins and needles in the lips, fingers or toes, irritability and hunger. Tell your doctor if you experience these symptoms.

If you experience any of these symptoms during treatment with CIPROFLOXACIN ALPHAPHARM, tell your doctor, nurse or pharmacist immediately.

CIPROFLOXACIN ALPHAPHARM may need to be discontinued.

Tell your doctor, pharmacist or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After receiving CIPROFLOXACIN ALPHAPHARM

When treatment is to be stopped, your doctor may need to alter the dose of other medicines accordingly and monitor your condition.

Each infusion bag of CIPROFLOXACIN ALPHAPHARM is to be used once only. Any unused portion remaining in the bag must be discarded.

Storage

CIPROFLOXACIN ALPHAPHARM will be stored in the pharmacy or on the ward.

The infusion bag is kept in a cool, dry place away from sunlight, where the temperature stays below 25°C.

The infusion bag should not be stored in the refrigerator or freezer.

The infusion bag should be stored in the outer overwrap in order to protect it from light.

If you have any further questions on CIPROFLOXACIN ALPHAPHARM, or are unsure of the information given above, please ask your doctor or nurse, who will be able to assist you.

Product description

What it looks like

CIPROFLOXACIN ALPHAPHARM is a clear, colourless to slightly yellow solution containing ciprofloxacin in the following strengths:

- 200 mg/100 mL infusion bag
- 400 mg/200 mL infusion bag

Each carton of CIPROFLOXACIN ALPHAPHARM contains 10 infusion bags.

Ingredients

Active Ingredients:

CIPROFLOXACIN ALPHAPHARM - 200 mg ciprofloxacin / 100 mL infusion bag

CIPROFLOXACIN ALPHAPHARM - 400 mg ciprofloxacin /
200 mL infusion bag

Inactive ingredients:

- lactic acid
- glucose monohydrate
- water for injections
- small amounts of hydrochloric acid to adjust the acidity of the solution

CIPROFLOXACIN ALPHAPHARM contains sugars.

Supplier

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

CIPROFLOXACIN ALPHAPHARM 200 mg /100 mL -
AUST R 154611

CIPROFLOXACIN ALPHAPHARM - 400 mg /200 mL -
AUST R 154612

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