

**Package leaflet: Information for the patient****Quinsair 240 mg nebuliser solution**
levofloxacin

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Quinsair is and what it is used for
2. What you need to know before you use Quinsair
3. How to use Quinsair
4. Possible side effects
5. How to store Quinsair
6. Contents of the pack and other information

1. What Quinsair is and what it is used for

Quinsair contains an antibiotic medicine called levofloxacin. It belongs to the group of antibiotics called fluoroquinolones.

Quinsair is used to treat **lung infections** caused by *Pseudomonas aeruginosa* in adults with **cystic fibrosis**. It is an antibiotic medicine that is breathed (inhaled) directly into the lungs where it kills the bacteria causing the infection. This helps to improve breathing in people with cystic fibrosis.

2. What you need to know before you use Quinsair**Do not use Quinsair:**

- if you are **allergic to levofloxacin**, to any other **quinolone antibiotics**, such as moxifloxacin, ciprofloxacin or ofloxacin, or to any of the other ingredients of this medicine (listed in section 6)
- if you have ever had a problem with your tendons (**inflammation of a tendon** or a **ruptured tendon**) during treatment with a **quinolone or fluoroquinolone antibiotic**
- if you suffer from **epilepsy**
- if you are **pregnant or breast-feeding**

Warnings and precautionsBefore taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Quinsair, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

When taking this medicine

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Quinsair therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Quinsair, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Tell your doctor before using Quinsair if you have or have ever had any of the following:

- **A severe allergic reaction.** Symptoms are listed in section 4.
- **Prolonged, disabling and potentially irreversible serious side effects.**
Fluoroquinolone/quinolone antibacterial medicines, including Quinsair, have been associated with rare but serious side effects, some of them being long lasting (continuing for months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, memory impairment, severe fatigue, and severe sleep disorders. There are no medicines that have been established as being effective treatments for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.

If you experience any of these side effects after taking Quinsair, then do not take any further doses and contact your doctor immediately. You and your doctor will decide on whether to continue treatment, considering alternative options.

Depression or mental health problems.

You may experience psychiatric reactions when taking Quinsair, including when taking it for the first time. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Quinsair. In rare cases, depression or psychosis can progress to thoughts of suicide or suicide attempts. If this happens, stop taking Quinsair and contact your doctor immediately. You may not notice some changes in your mood and behaviour so it is very important to tell your friends and family that you are taking Quinsair, and that there may be rare psychiatric side effects. Others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about.

Severe kidney problems.Severe skin reactions

If you are treated with Quinsair, you may have a severe skin reaction such as blistering or lesions. Tell your doctor if you notice any skin reactions after using Quinsair.

Liver problems. Symptoms are listed in section 4.Heart rhythm abnormalities

Quinsair can cause changes to your heart rhythm, especially if you are taking any medicines to treat heart problems or low levels of potassium or magnesium in the blood. Women who take these types of medicines may be more likely to be affected. If you experience palpitations or an irregular heart beat whilst using Quinsair you should tell your doctor immediately.

Seizures and convulsions

Quinolone antibiotics, including Quinsair, may cause seizures or convulsions (fits). If this happens, stop using Quinsair and contact your doctor immediately.

Nerve damage

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Quinsair and inform your doctor immediately in order to prevent the development of this potentially irreversible condition.

A disease causing muscle weakness and fatigue called myasthenia gravis.Inflammation of a tendon causing pain, stiffness and/or swelling in the joints (tendonitis).

If you have experienced difficulty in breathing after receiving Quinsair which can range from mild to severe (bronchospasm).

Coughing up blood or blood-stained mucus from the airways.Glucose-6-phosphate dehydrogenase deficiency

Quinolone antibiotics, such as Quinsair, can cause patients with glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease) to be prone to blood complications leading to a sudden rise in body temperature, yellowing of the skin and mucous membranes, dark coloured urine, paleness, tiredness, heavy, fast breathing and a weak, rapid pulse. Talk to your doctor if you have any questions about this.

Diabetes

Quinolone antibiotics, including Quinsair, may cause levels of glucose in the blood to be either too high or too low. If you are diabetic, you should monitor your blood glucose levels carefully.

Diarrhoea

You may develop diarrhoea during or after your treatment with Quinsair. If this becomes severe or persistent, or you notice blood in your stools, you should stop using Quinsair immediately and talk to your doctor. Do not take any medicines to treat your diarrhoea without first checking with your doctor.

Resistance to antibiotics

Bacteria can become resistant to treatment with an antibiotic over time. This means that Quinsair should not be used to prevent lung infections. It should only be used to treat lung infections caused by *Pseudomonas aeruginosa*. Talk to your doctor if you have any concerns or questions about this.

Superinfections

Sometimes lengthy treatment with antibiotics can mean that you get another infection caused by other bacteria which are not affected by the antibiotic (superinfection). Talk to your doctor if you have any concerns or questions about this and using Quinsair.

Vision problems

If you notice any changes in your eyesight or any other problems with your eyes whilst using Quinsair, contact an eye specialist immediately.

Photosensitivity

Quinsair may make your skin become more sensitive to sunlight. You should avoid prolonged exposure to sunlight or strong sunlight and should not use sunbeds or any other UV

lamps whilst using Quinsair and for 48 hours after stopping treatment.

False test results

Certain tests (e.g. to confirm tuberculosis or screening for strong painkillers) may give false results whilst you are being treated with Quinsair.

- If you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).

- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

- if you have been diagnosed with leaking heart valves (heart valve regurgitation).

- if you have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).

If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.

If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

Children and adolescents

Quinsair should not be given to children and adolescents less than 18 years old as there is not enough information about its use in this age group.

Other medicines and Quinsair

Tell your doctor or a pharmacist if you are taking, have recently taken or might take any other medicines. These medicines may interfere with the effects of Quinsair.

Tell your doctor if you are taking any of the following medicines:

- Vitamin K antagonists such as **warfarin** (used to prevent blood clots). Taking these medicines with Quinsair may lead to an increase in bleeding. Your doctor may need to give you regular blood tests to check how well your blood can clot.

- **Theophylline** (used to treat breathing problems) or non-steroidal anti-inflammatory medicines (NSAIDs) such as **fenbufen, aceclofenac or ibuprofen**. Taking Quinsair at the same time as these medicines could increase your risk of a fit (seizure).

- Medicines such as **probenecid** (used to prevent gout) or **cimetidine** (used to treat ulcers). Taking Quinsair at the same time as these medicines could affect how your kidneys deal with the medicine which is particularly important if you suffer from kidney problems.

- **Ciclosporin** (used after organ transplants) or **medicines that affect your heart beat** (such as antiarrhythmics, tricyclic antidepressants, macrolide antibiotics or antipsychotics). Quinsair can interfere with the effects of these medicines. Your doctor will explain more.

Pregnancy and breast-feeding

Quinsair must not be used whilst pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Quinsair may make you feel dizzy, tired or weak, or cause problems with your eyesight. If this happens to you, do not drive or use any tools or machines.

3. How to use Quinsair

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

How much do I use?

Inhale the contents of **one ampoule (240 mg) twice a day using the Zirela Nebuliser System**. It takes about 5 minutes to inhale the medicine using the nebuliser.

When do I use it?

Inhaling Quinsair at the same time each day will help you remember when to take your medicine. Inhale your medicine as follows:

- 1 ampoule in the morning using the Zirela Nebuliser
- 1 ampoule in the evening using the Zirela Nebuliser

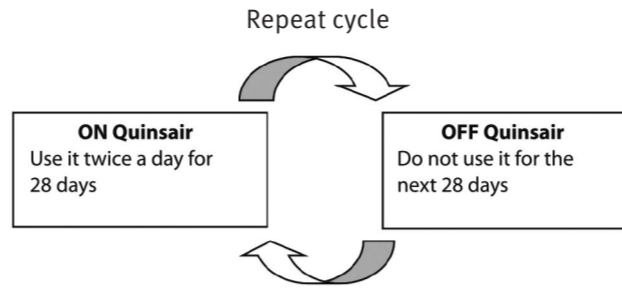
It is best to leave close to 12 hours between your doses.

How long do I use it for?

You use Quinsair every day for 28 days, then take a 28-day break, during which you do not inhale any Quinsair. You then start another treatment course.

It is important that you keep using the medicine twice a day during your 28 days on treatment and that you keep to the 28-days on, 28-

days off cycle for as long as your doctor tells you to.

**If you experience breathing difficulties when you use Quinsair what additional medicine may your doctor prescribe for you?**

If you experience breathing difficulties after using Quinsair, your doctor may prescribe you an inhaler containing a bronchodilator medicine (e.g. salbutamol). Inhale this medicine at least 15 minutes or up to 4 hours before your next dose of Quinsair.

What if I am using several different inhalers and other therapies for cystic fibrosis?

If you are using several different inhaled treatments and other therapies for cystic fibrosis, it is recommended that you use your medicines in the following order:

- 1st Bronchodilators
- 2nd Dornase alfa
- 3rd Airway clearance techniques
- 4th Quinsair
- 5th Inhaled steroids

How to use it

Quinsair should be taken by inhalation using a **Zirela Nebuliser Handset** (including a Zirela Aerosol Head). This should be connected to either an eBase Controller or an eFlow rapid Control Unit.

Important information to know before you start

- Each ampoule is for **single use only. Once an ampoule is opened, the contents should be used immediately.**
 - Do not use Quinsair if you notice that the sealed foil sachet or ampoules have been tampered with.
 - Do not use Quinsair if you notice that it is cloudy or there are particles in the solution.
 - **Do not mix Quinsair with any other medicines** in the Zirela Nebuliser Handset.
 - Do not put any medicines other than Quinsair in the Zirela Nebuliser Handset.
 - Do not try to inhale Quinsair using any other type of nebuliser handset.
 - Check that your Zirela Nebuliser System works properly before starting your treatment.
 - Do not swallow the liquid in the ampoule.
- Carefully read the Manufacturer's Instructions for Use, provided with your Zirela Nebuliser Handset.

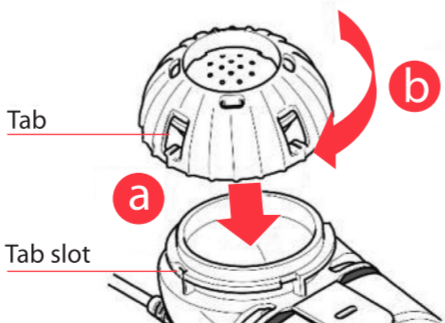
How do I prepare my Nebuliser System to inhale the medicine?

Keep the Zirela Instructions for Use in a safe place as they give full details on assembling the device.

- 1) **Make sure that the Zirela Nebuliser Handset** is on a flat and stable surface.
- 2) **Squeeze all of the contents of one ampoule** into the medicine reservoir of the Zirela Nebuliser Handset (Figure 1). Ensure that you completely empty the ampoule, gently tapping it against the side of the reservoir if necessary.

**Figure 1**

- 3) **Close the medicine reservoir** by aligning the tabs of the medicine cap with the slots of the reservoir (a). Press down and turn the cap clockwise as far as it will go (b, Figure 2).

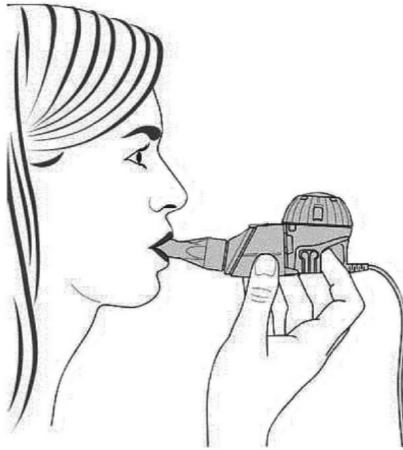
**Figure 2****How do I use the Zirela Nebuliser System?**

- 1) **When you start your treatment**, sit in a relaxed, upright position.

- 2) **Hold the handset level**, press and hold the on/off button on the controller for a few seconds. You will hear one "beep" and the status light will turn green.

- 3) **After a few seconds, an aerosol mist will begin to flow** into the aerosol chamber of the Zirela Nebuliser Handset. If aerosol mist does not begin to flow, please refer to the Zirela Manufacturer's Instructions for Use for help.

- 4) **Keeping the handset level**, place the mouthpiece in your mouth and close your lips around it (Figure 3).

**Figure 3**

- 5) **Breathe normally** (inhale and exhale) through the mouthpiece. Try not to breathe through your nose. Continue to inhale and exhale comfortably until the treatment is finished. It takes about 5 minutes to inhale the medicine using the nebuliser.

- 6) **When all of the medicine has been delivered**, you will hear two "beeps", which means the treatment is complete.

- 7) **Once complete, open the medicine cap** to ensure all of the medicine has been used. A few drops of the medicine may remain at the bottom of the reservoir at the end of treatment. This is ok. However if there are more than a few drops left, replace the medicine cap and restart treatment from step 1.

- 8) **Once treatment is complete**, disconnect the controller and take apart the Zirela Nebuliser Handset for cleaning and disinfecting. The Manufacturer's Instructions for Use will give full details on cleaning and disinfecting.

What if I need to stop my treatment before I've finished?

If for any reason you must stop the treatment before it's finished, press and hold the controller's on/off button for one second. After it has completely turned itself off and when you are ready to restart, press and hold the on/off button for one second again. Treatment will restart. You must inhale and exhale through the mouthpiece as before.

How and when do I replace the Zirela Nebuliser Handset?

One nebuliser handset should be used for one 28-day treatment course. Please refer to the Manufacturer's Instructions for Use for cleaning and storage advice.

If you use more Quinsair than you should

If you have used more Quinsair than you should, **tell your doctor as soon as possible**. You may experience symptoms like irregular heartbeat, which needs to be checked by your doctor. If the contents of the ampoule are swallowed, don't worry but tell your doctor as soon as possible.

If you forget to use Quinsair

If you forget a dose, use it as soon as you remember as long as there is an 8-hour interval before inhaling the next dose. However if it is nearly the time for your next dose, skip the missed dose.

Do not inhale the contents of more than one ampoule to make up for a missed dose.

If you stop using Quinsair

Do not stop using Quinsair without first talking to your doctor as your lung infection may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious

- Get **urgent medical treatment immediately** if you notice a **severe allergic reaction** after inhaling Quinsair. Symptoms include:
- General itching and feeling of heat - especially affecting the scalp, mouth, throat, palms or soles of your feet
 - Severe wheezing, or noisy or difficult breathing
 - Severe hives/nettle rash
 - Swelling of the lips, face, throat or tongue
 - Pale or greyish skin colour
 - A fast heart beat
 - Faintness or passing out

Stop using Quinsair and tell your doctor immediately:

- if you experience **pain, stiffness and/or swelling in your joints**
- if you develop **problems with your liver**. Symptoms include:
 - Loss of appetite
 - Yellowing of the skin and eyes (jaundice)
 - Dark coloured urine

- Itching
- Tenderness (pain) around the stomach (abdomen)

Other side effects can include:

Very common: may affect more than 1 in 10 people

- Cough
- Abnormal sense of taste
- Tiredness, weakness and lower tolerance to exercise
- Loss of appetite
- Shortness of breath
- Changes in the amount and thickness of mucus/phlegm
- Coughing up blood
- Decreased amount of air that can be breathed out in one second (decreased FEV1 test)

Common: may affect up to 1 in 10 people

- Fungal infection around vagina
- Insomnia or difficulty sleeping
- Headache
- Dizziness
- Ringing or noise in the ears (tinnitus)
- Change to the voice
- Feeling and being sick
- Abdominal pain
- Diarrhoea
- Constipation
- Rash
- Joint or muscle pain
- Fever
- Abnormal blood test results (increased levels of certain liver enzymes or bilirubin in the blood, and decreased kidney function test)
- Decreased lung function test
- Increased or decreased amount of sugar (glucose) in the blood
- Abnormal breathing sounds

Uncommon: may affect up to 1 in 100 people

- Fungal infection of the mouth
- Low numbers of red cells in the blood (anaemia) or the cells in the blood that help it clot (platelets)
- Low or high numbers of white cells in the blood
- Feeling anxious, restless or agitated and/or depressed
- Reduced sense of smell
- Feeling sleepy
- Changes in eyesight
- Loss of hearing
- Increased heart beat
- Difficulty in breathing
- Retching
- Indigestion
- Passing wind
- Hives/nettle rash and itching
- Chest wall pain
- Kidney failure
- Changes in heart rhythm
- Pain, burning, tingling, numbness and/or weakness in the limbs (neuropathy)

The following side effects have also been reported after taking tablets or an intravenous infusion containing levofloxacin, so they might possibly occur after using Quinsair:

Uncommon: may affect up to 1 in 100 people

- Feeling confused or nervous
- Shaking
- Sensation of dizziness, spinning or falling over (vertigo)
- Excessive sweating

Rare: may affect up to 1 in 1,000 people

- Cases of long lasting (up to months or years) or permanent adverse drug reactions, have been associated with quinolone and fluoroquinolone antibiotics. These may include tendon inflammation, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, pricking, burning, numbness or pain (neuropathy), fatigue, sleep disorders, memory impairment, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, as well as impairment of hearing, vision, and taste and smell. There are no medicines that have been established as being effective treatments for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.
- Hallucinations and/or feeling paranoid
- Feeling agitated
- Unusual dreams or nightmares
- Convulsions (fits)
- Tingling sensation (pins and needles) and/or numbness
- Palpitations
- Low blood pressure
- Muscle weakness
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms)
- Sharply demarcated, erythematous patches with/without blistering

Not known: frequency cannot be estimated from the available data

- Low numbers of all types of cells in the blood
- Diabetic coma
- Severe mental problems (which in very rare cases may lead to self-harm)
- Pain, burning, tingling, numbness and/or weakness in the limbs (neuropathy)
- Involuntary muscle movements, twitching or spasms

- Fainting
- Severe throbbing headaches with loss of eyesight
- Temporary loss of vision
- Rapid or abnormal heart beat
- Inflammation of the lung
- Severe skin reactions such as painful blistering or lesions possibly in the mouth, nose or vagina
- Increased sensitivity of the skin to sunlight or UV light (sunbeds or other UV lamps)
- Inflammation of the blood vessels
- Inflammation of the mouth or lips
- Rapid breakdown of muscles
- Inflammation of a tendon or a broken tendon
- Pain including pain in the back, chest, arms and legs and arms

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Quinsair

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

Do not use this medicine after the expiry date which is stated on the ampoule, the foil sachet and the boxes after EXP. The expiry date refers to the last day of that month.

Each ampoule is for single use only. Once an ampoule is opened, the contents should be used immediately. Any unused product must be thrown away. Replace any unused, unopened ampoules from the strip back into the sachet to protect them from light.

Store in the original package in order to protect from light. This medicine does not require any special temperature storage conditions.

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