

Moxifloxacin Kabi

Moxifloxacin Hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Moxifloxacin Kabi.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving Moxifloxacin Kabi 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 in a safe place, even after your treatment is finished.

You may need to read it again.

What Moxifloxacin Kabi is used for

Moxifloxacin Kabi is a sterile intravenous antibiotic used in adults for the treatment of serious infections of the lungs and airways. It can also be used to treat severe, complicated skin and skin structure infections.

Moxifloxacin Kabi is used to start the treatment and then your doctor may prescribe tablets to complete the course.

Remember to read the Consumer Medicine Information for Moxifloxacin tablets, if you receive them, because it may contain

additional information specific to the tablets.

Moxifloxacin Kabi contains the active ingredient, moxifloxacin, which is an antibiotic belonging to a group of medicines called quinolones. These antibiotics work by killing the bacteria that are causing your infection.

Moxifloxacin Kabi will not work against infections caused by viruses such as colds or the flu.

Moxifloxacin Kabi is available by prescription only, and is used in a hospital environment only.

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 Moxifloxacin Kabi

When you must not be given it

You must not be given Moxifloxacin Kabi if you have an allergy to:

- moxifloxacin, the active ingredient in Moxifloxacin Kabi
- any of the ingredients listed at the end of this leaflet.
- other medicines belonging to the quinolone family (e.g. ciprofloxacin, norfloxacin, nalidixic acid)

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
- rash, itching or hives on the skin

You should not be given Moxifloxacin Kabi if you:

- have a condition called 'QTc prolongation' which is a type of abnormal heart rhythm
- are taking medicines to treat arrhythmia – fast, slow or irregular heart beat (e.g. quinidine, procainamide, amiodarone, sotalol)
- have a blood test that shows lower than normal potassium levels

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 think you may be pregnant. Moxifloxacin Kabi is not recommended if you are pregnant.

Tell your doctor if you are breastfeeding.

Moxifloxacin Kabi passes into breast milk and may affect your baby.

Moxifloxacin Kabi should not be used in children under 18 years of age.

Tell your doctor if you:

- or someone in your family has a history of heart rhythm problems
- are taking any medicine that might affect heart rhythm (e.g. quinidine, procainamide, amiodarone, sotalol, erythromycin, tricyclic antidepressants, antipsychotics)
- have low potassium levels
- have had any condition affecting the brain, particularly if you have ever had a seizure ('fit')
- have severe liver problems
- have a condition called myasthenia gravis (a disease causing muscle weakness)
- have or have had a mental illness
- have diabetes

Some medical conditions may require a restricted sodium intake (e.g. congestive heart failure, kidney failure, kidney disease). Tell your doctor if you have a condition like this because Moxifloxacin Kabi solution contains sodium salt. The additional sodium you receive may worsen the symptoms of these conditions.

If you have not told your doctor about any of the above, tell him/her before you are given Moxifloxacin Kabi.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those that you buy without a

prescription from your pharmacy, supermarket or health food shop.

Moxifloxacin Kabi may have an effect on the electro-cardiogram (ECG – an electrical record of the activity of the heart) and may add to the effect of other medicines on the ECG. You should advise your doctor if you are taking any medicines that might affect the heart rhythm.

In particular, tell your doctor if you are taking:

- warfarin, a medicine used to stop blood clots. Your doctor should perform INR testing and may adjust your warfarin dose
- medicines used to treat abnormal heart rhythm (e.g. quinidine, procainamide, amiodarone, sotalol)
- medicines that can affect the heart rhythm (e.g. erythromycin, tricyclic antidepressants, antipsychotics)
- corticosteroids

These medicines and Moxifloxacin Kabi may affect each other or increase the chance of you getting a side effect.

Your doctor or pharmacist will be able to tell you what to do when receiving Moxifloxacin Kabi with other medicines.

How Moxifloxacin Kabi is given

Moxifloxacin Kabi is given as a slow injection into a vein over a period of 60 minutes ('drip').

Moxifloxacin Kabi must only be given by a doctor or a nurse.

How much is given

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

The usual adult dose is 400mg once a day for 5-21 days.

How long it is given

Your doctor will determine the duration of time that you are given Moxifloxacin Kabi depending on your infection. Your doctor will put you on Moxifloxacin tablets as soon as possible, after being given Moxifloxacin Kabi injection.

If you are given too much (overdose)

Immediately tell your doctor or nurse or telephone the Poisons Information Centre (Australia: 13 11 26) or 0800 764 766 (New Zealand), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have received too much Moxifloxacin Kabi. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are receiving Moxifloxacin Kabi

Things you must do

Tell your doctor or nurse if you develop an allergic reaction (e.g. skin rash) while on Moxifloxacin Kabi, even following a single dose.

If you develop diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have finished receiving Moxifloxacin Kabi. Diarrhoea may mean that you have a serious

condition affecting your bowel. You may need urgent medical care. Do not take any medications for diarrhoea without checking with your doctor.

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

Medicines like Moxifloxacin Kabi have been reported to cause tendon damage (especially the Achilles tendon). Elderly patients and those taking a type of medicine called corticosteroids are more at risk.

If you experience palpitations (fast or irregular heartbeats) or fainting spells during the period of treatment, tell your doctor immediately.

Tell your doctor or nurse if you experience symptoms of depression or self-endangering behavior. Moxifloxacin Kabi should be discontinued.

Tell your doctor or nurse if you develop photosensitivity (getting sunburnt very easily). Avoid exposure to ultraviolet radiation and sunlight. Protect your skin when you are in the sun, especially between 10am and 3pm. If you are outdoors, wear protective clothing and use a 30+ sunscreen.

Tell your doctor or nurse as soon as possible if you develop pain, burning tingling, numbness or weakness in any part of the body.

Things you must not do

Do not interfere with the equipment that is used to infuse Moxifloxacin Kabi into your body. Changes to the settings of the equipment must only be carried

out by your doctor or the nurse who is looking after you.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need to stop receiving the injection or have medical treatment if you get some of the serious side effects.

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

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

Tell your doctor if you notice any of the following side effects and they worry you:

- headache
- dizziness or light-headedness
- nausea, vomiting
- stomach pains, diarrhoea
- thrush in the mouth (sore creamy-yellow raised patches in mouth) or in the vagina (itching, burning or thick white discharge)
- redness or pain at the site of injection

These are the more common side effects of Moxifloxacin Kabi. They are usually mild and short-lived.

Tell your doctor immediately, if you notice any of the following:

- allergic reactions such as skin rashes, swelling of the face, lips, mouth or throat

- palpitations or fainting spells
- watery or bloody diarrhoea, even if it occurs several weeks after finishing your Moxifloxacin Kabi treatment
- pain, swelling or rupture of a tendon
- fits (seizures, convulsions)
- pain, burning, tingling, numbness or weakness that starts or worsens on Moxifloxacin Kabi
- changes in your moods or thoughts that worry you

These are serious side effects. If you have them, you may need urgent medical attention, and Moxifloxacin Kabi will need to be discontinued.

Moxifloxacin Kabi may cause rapid and severe inflammation of the liver, which can lead to life-threatening liver failure including fatal cases. Tell your doctor immediately if you suddenly feel unwell or sick and develop symptoms such as:

- yellowing of the skin and in the whites of your eyes, also called jaundice
- pain in liver area
- dark urine
- itchy skin
- tendency to bleed

If you develop a skin reaction or blistering and/or peeling of the skin and/or mucosal reactions contact your doctor immediately before you continue the treatment.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After receiving Moxifloxacin Kabi

Storage

Moxifloxacin Kabi will be stored in the pharmacy or on the ward. It is kept in a cool, dry place away from sunlight, where the temperature stays below 25°C and above 15°C. Do not refrigerate or freeze.

Disposal

Each pack of Moxifloxacin Kabi is to be used once only. Any unused portion must be returned to the pharmacist for disposal.

Product Description

What it looks like

Moxifloxacin Kabi 400 mg is a ready to use, clear yellow solution for infusion.

Moxifloxacin Kabi is available in Freeflex bags in packs of 1, 10, 20, 25 and 40.

It is also available in KabiPac bottles in packs of 1, 10, 20, 25 and 40.

Not all forms and pack sizes may be marketed.

Ingredients

Active Ingredient:

Moxifloxacin Kabi - moxifloxacin (as hydrochloride) 400 mg per 250 mL

Inactive ingredients:

- sodium acetate trihydrate
- sodium sulphate
- sulphuric acid
- water for injections

Supplier

Moxifloxacin Kabi is supplied in Australia by:

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (02) 9391 5555

Moxifloxacin Kabi is supplied in New Zealand by:

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

Australian Registration Numbers

Freeflex bag - AUST R 241252

KabiPac bottle – AUST R 241253

Date of preparation

May 2016.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.