

Package leaflet: Information for the patient

ERELAN 400mg film-coated tablets

For use in adults

Moxifloxacin

Read all of this leaflet carefully before you start taking 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 Erelan is and what it is used for
2. What you need to know before you take Erelan
3. How to take Erelan
4. Possible side effects
5. How to store Erelan
6. Contents of the pack and other information

1. What Erelan is and what it is used for

Erelan contains the active substance moxifloxacin, which belongs to a group of antibiotics called fluoroquinolones. Moxifloxacin works by killing bacteria that cause infections.

Erelan is used in patients aged 18 years and above for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Erelan should only be used to treat these infections when usual antibiotics cannot be used or have not worked:

- Infection of the sinuses, sudden worsening of long term inflammation of the airways or infection of the lungs (pneumonia) acquired outside the hospital (except severe cases).
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane.

Moxifloxacin tablets are not sufficient on their own for treating this kind of infection. Therefore, another antibiotic in addition to moxifloxacin should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section 2).

If the following bacterial infections have shown improvement during initial treatment with moxifloxacin solution for infusion, moxifloxacin tablets may also be prescribed by your doctor to complete the course of therapy:

- Infection of the lungs (pneumonia) acquired outside the hospital, infections of the skin and soft tissue.

Erelan tablets should not be used to initiate therapy for any type of infections of the skin and soft tissue or in severe infections of the lungs.

2. What you need to know before you take Erelan

Do not take Erelan:

- If you are allergic to moxifloxacin or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or are breast-feeding.
- If you are under 18 years of age.
- If you were born with or have:
 - Any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart).
 - A salt imbalance in the blood (especially low levels of potassium or magnesium in the blood).
 - A very slow heart rhythm (called ‘bradycardia’).
 - A weak heart (heart failure).
 - A history of abnormal heart rhythms.
- or
- If you are taking other medicines that result in abnormal ECG changes (see section “Other medicines and Erelan”). This is because moxifloxacin can cause changes on the ECG, that is a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.
- If you have a severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Erelan, 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.

Talk to your doctor or pharmacist before taking Erelan:

- If you are diabetic because you may experience a risk of change in blood sugar levels with moxifloxacin.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking moxifloxacin.
- Moxifloxacin can change your heart’s ECG, especially if you are female, or if you are elderly. If you are currently taking any medicine that decreases your blood potassium levels, consult your doctor before taking Erelan (see also sections “Do not take” and “Other medicines and Erelan”).
- 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, Behcet’s disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).
- If you suffer from epilepsy or a condition which makes you likely to have convulsions talk to your doctor before taking Erelan.
- If you have or have ever had any mental health problems, consult your doctor before taking Erelan.
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking moxifloxacin may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your doctor, who will advise whether Erelan is suitable for you.
- If you have a complicated infection of the female upper genital tract (e.g. associated with an abscess of the fallopian tubes and ovaries or of the pelvis), for which your doctor considers an intravenous treatment necessary, treatment with moxifloxacin tablets is not appropriate.

- For the treatment of mild to moderate infections of the female upper genital tract your doctor should prescribe another antibiotic in addition to moxifloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

While taking Erelan:

- 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.

When taking Erelan

- If you experience palpitations or irregular heart beat during the period of treatment, you should inform your doctor immediately. He/she may wish to perform an ECG to measure your heart rhythm.
- The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed.
- There is a rare chance that you may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock) even with the first dose. Symptoms include tightness in the chest, feeling dizzy, feeling sick or faint, or dizziness when standing up. If so, stop taking Erelan and seek medical advice immediately.
- Moxifloxacin may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases, see section 4). If you suddenly feel unwell and/or are being sick and also have yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or liver induced disease of the brain (symptoms of a reduced liver function or a rapid and severe inflammation of the liver) please contact your doctor before taking any more tablets.
- Quinolone antibiotics, including moxifloxacin, may cause convulsions. If this happens, stop taking Erelan and contact your doctor immediately.
- 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 Erelan and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- You may experience mental health problems even when taking quinolone antibiotics, including moxifloxacin, for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts (see section 4). If you develop such reactions, stop taking Erelan and inform your doctor immediately.
- You may develop diarrhoea whilst or after taking antibiotics including moxifloxacin. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Erelan immediately and consult your doctor. You should not take medicines that stop or slow down bowel movement.
- 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 Erelan therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Erelan, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- If you are elderly and have kidney problems make sure that you drink plenty whilst taking moxifloxacin. If you get dehydrated this may increase the risk of kidney failure.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately (see section "Driving and using machines" and section 4).

- Fluoroquinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycemia), or lowering of your blood sugar levels below normal levels (hypoglycaemia), potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4). If you suffer from diabetes, your blood sugar should be carefully monitored.
- Quinolone antibiotics may make your skin become more sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking moxifloxacin (see section 4. Possible side effects).
- The efficacy of moxifloxacin in the treatment of severe burns, infections of deep tissue and diabetic foot infections with osteomyelitis (infections of the bone marrow) has not been established.

Serious skin reactions

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis (AGEP) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported with the use of moxifloxacin.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a serious rash or another of these skin symptoms, stop taking moxifloxacin and contact your doctor or seek medical attention immediately.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including Erelan, have been associated with very rare but serious side effects, some of them being long lasting (continuing 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, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking Erelan, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because efficacy and safety have not been established for this age group (see section “Do not take Erelan”).

Other medicines and Erelan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

For Erelan, be aware of the following:

- If you are taking moxifloxacin and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, do not take moxifloxacin together with the following medicines:

- Medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide).
- Antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride).
- Tricyclic antidepressants.
- Some antimicrobials (e.g. saquinavir, sparfloxacin, intravenous erythromycin, pentamidine, antimalarials particularly halofantrine).
- Some antihistamines (e.g. terfenadine, astemizole, mizolastine).
- Other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).
- You must tell your doctor if you are taking other medicines that can lower your blood potassium levels (e.g. some diuretics, some laxatives and enemas [high doses] or corticosteroids [anti-inflammatory drugs], amphotericin B) or cause a slow heart rate because these can also increase the risk of serious heart rhythm disturbances while taking moxifloxacin.
- Any medicine containing magnesium or aluminium (such as antacids for indigestion), iron, zinc or didanosine or any medicine containing sucralfate (to treat stomach disorders) can reduce the action of moxifloxacin tablets. Take your moxifloxacin tablet 6 hours before or after taking the other medicine.
- Taking any medicine containing charcoal at the same time as Erelan reduces the action of moxifloxacin. It is recommended that these medicines are not used together.
- If you are currently taking drugs to thin your blood (oral anti-coagulants such as warfarin), it may be necessary for your doctor to monitor your blood clotting time.

Erelan with food, drink and alcohol

Erelan can be taken with or without food (including dairy products).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Erelan if you are pregnant or breast-feeding.

Animal studies do not indicate that your fertility will be impaired by taking this medicine.

Driving and using machines

Moxifloxacin may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision, or you may faint for a short period. If you are affected do not drive or operate machinery.

Erelan contains lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Erelan

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

The recommended dose for adults is one 400mg film-coated tablet once daily.

Erelan tablets are for oral use. Swallow the tablet whole (to mask the bitter taste) and with plenty of liquid. You can take Erelan with or without food. Try to take the tablet at approximately the same time each day.

The same dose can be taken by elderly patients, patients with a low bodyweight or in patients with kidney problems.

The time you will take Erelan for depends on your infection.

Unless your doctor tells you otherwise, your treatment will be as follows:

- For sudden worsening (acute exacerbation) of chronic bronchitis 5 - 10 days.
- For infection of the lungs (pneumonia) except for pneumonia which starts during a stay in hospital 10 days.
- For acute infection of the sinuses (acute bacterial sinusitis) 7 days.
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infection of the fallopian tubes and infection of the uterus mucous membrane 14 days.

When Erelan film-coated tablets are used to complete a course of therapy started with moxifloxacin solution for infusion, the recommended durations of use are:

- Infection of the lungs (pneumonia) acquired outside the hospital 7 -14 days.
Most patients with pneumonia were switched to oral treatment with Erelan film-coated tablets within 4 days.
- Infections of the skin and soft tissue 7 -21 days.
Most patients with infections of the skin and soft tissue were switched to oral treatment with Erelan film-coated tablets within 6 days.

It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking Erelan too soon your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to moxifloxacin.

The recommended dose and duration of treatment should not be exceeded (see section 2).

If you take more Erelan than you should

If you take more than the prescribed one tablet a day, get medical help immediately.

Try to take any remaining tablets, the packaging or this leaflet with you to show the doctor or pharmacist what you have taken.

If you forget to take Erelan

If you forget to take your tablet you should take it as soon as you remember on the same day. If you do not remember on the same day, take your normal dose (one tablet) on the next day.

Do not take a double dose to make up for a forgotten dose.

If you are unsure about what to do ask your doctor or pharmacist.

If you stop taking Erelan

If you stop taking this medicine too soon your infection may not be completely cured. Talk to your doctor if you wish to stop taking your tablets before the end of the course of treatment.

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.

The **most serious side effects** observed during treatment with moxifloxacin are listed below.

If you notice:

- An abnormal fast heart rhythm (rare side effect).
- That you suddenly start feeling unwell or notice yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or disturbances of thought or wakefulness (these can be

signs and symptoms of fulminant inflammation of the liver potentially leading to life-threatening liver failure (very rare side effect, fatal cases have been observed)).

- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency of this side effect is 'not known').
- 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 which is also known as DRESS or drug hypersensitivity syndrome) (frequency of this side effect is 'not known').
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH) (very rare side effect).
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma) (very rare side effect).
- Inflammation of blood vessels (signs could be red spots on your skin, usually on your lower legs or effects like joint pain) (very rare side effect).
- A severe, sudden generalised allergic reaction incl. very rarely a life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse) (rare side effect).
- Swelling incl. swelling of the airway (rare side effect, potentially life-threatening).
- Convulsions (rare side effect).
- Troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (rare side effect).
- Depression (in very rare cases leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (rare side effect).
- Insanity (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (very rare side effect).
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis incl. pseudomembranous colitis), which in very rare circumstances, may develop into complications that are life-threatening (rare side effects).
- Pain and swelling of the tendons (tendonitis) (rare side effect) or a tendon rupture (very rare side effect).
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis) (frequency of this side effect is 'not known').

Stop taking this medicine and tell your doctor immediately as you may need urgent medical advice.

In addition, if you notice

- transient loss of vision (very rare side effect), **contact an eye specialist immediately.**

If you have experienced life-threatening irregular heart beat (Torsade de Pointes) or stopping of heart beat while taking moxifloxacin (very rare side effects), **tell your treating doctor immediately that you have taken this medicine and do not restart the treatment.**

A worsening of the symptoms of myasthenia gravis has been observed in very rare cases. If this happens, **consult your doctor immediately.**

If you suffer from diabetes and you notice that your blood sugar is increased or decreased (rare or very rare side effect), **inform your doctor immediately.**

If you are elderly with existing kidney problems and you notice decrease in urine output, swelling in your legs, ankles or feet, fatigue, nausea, drowsiness, shortness of breath or confusion (these can be signs and symptoms of kidney failure, a rare side effect), **consult your doctor immediately**.

Other side effects which have been observed during treatment with moxifloxacin are listed below by how likely they are.

Common (may affect up to 1 in 10 people)

- Nausea.
- Diarrhoea.
- Dizziness.
- Stomach and abdominal ache.
- Vomiting.
- Headache.
- Increase of a special liver enzyme in the blood (transaminases).
- Infections caused by resistant bacteria or fungi e.g. oral and vaginal infections caused by Candida.
- Change of the heart rhythm (ECG) in patients with low blood potassium level.

Uncommon (may affect up to 1 in 100 people)

- Rash.
- Stomach upset (indigestion/heartburn).
- Changes in taste (in very rare cases loss of taste).
- Sleep problems (predominantly sleeplessness).
- Increase of a special liver enzyme in the blood (gamma-glutamyl-transferase and/or alkaline phosphatase).
- Low number of special white blood cells (leukocytes, neutrophils).
- Constipation.
- Itching.
- Sensation of dizziness (spinning or falling over).
- Sleepiness.
- Wind.
- Change of the heart rhythm (ECG).
- Impaired liver function (incl. increase of a special liver enzyme in the blood (LDH)).
- Decreased appetite and food intake.
- Low white blood cells count.
- Aches and pains such as back, chest, pelvic and extremities pains.
- Increase of special blood cells necessary for blood clotting.
- Sweating.
- Increased specialised white blood cells (eosinophils).
- Anxiety.
- Feeling unwell (predominantly weakness or tiredness).
- Shaking.
- Joint pain.
- Palpitations.
- Irregular and fast heartbeat.
- Difficulty in breathing incl. asthmatic conditions.
- Increase of a special digestive enzyme in the blood (amylase).
- Restlessness / agitation.
- Tingling sensation (pins and needles) and/or numbness.
- Skin hives.
- Widening of blood vessels.
- Confusion and disorientation.
- Decrease of special blood cells necessary for blood clotting.

- Visual disturbances incl. double and blurred vision.
- Decreased blood clotting.
- Increased blood lipids (fats).
- Low red blood cell count.
- Muscle pain.
- Allergic reaction.
- Increase of bilirubin in the blood.
- Inflammation of the stomach.
- Dehydration.
- Severe heart rhythm abnormalities.
- Dry skin.
- Angina pectoris.

Rare (may affect up to 1 in 1,000 people)

- Muscle twitching.
- Muscle cramp.
- Hallucination.
- High blood pressure.
- Swelling (of the hands, feet, ankles, lips, mouth, throat).
- Low blood pressure.
- Kidney impairment (incl. increase in special kidney laboratory test results like urea and creatinine).
- Inflammation of the liver.
- Inflammation of the mouth.
- Ringing/noise in the ears.
- Jaundice (yellowing of the whites of the eyes or skin).
- Impairment of skin sensation.
- Abnormal dreams.
- Disturbed concentration.
- Difficulty in swallowing.
- Changes in smell (incl. loss of smell).
- Balance disorder and poor co-ordination (due to dizziness).
- Partial or total loss of memory.
- Hearing impairment including deafness (usually reversible).
- Increased blood uric acid.
- Emotional instability.
- Impaired speech.
- Fainting.
- Muscle weakness.

Very rare (may affect up to 1 in 10,000 people)

- Inflammation of joints.
- Abnormal heart rhythms.
- Increase of skin sensitivity.
- A feeling of self-detachment (not being yourself).
- Increased blood clotting.
- Muscle rigidity.
- Significant decrease of special white blood cells (agranulocytosis).
- A drop in the number of red and white blood cells and platelets (pancytopenia).

Not known (frequency cannot be estimated from the available data)

- Increased sensitivity of the skin to sunlight or UV light (see also section 2, Warnings and precautions).

- Sharply demarcated, erythematous patches with/without blistering that develop within hours of administration of moxifloxacin and heals with post inflammatory residual hyperpigmentation; it usually recurs at the same site of the skin or mucous membrane upon subsequent exposure to moxifloxacin.

Furthermore, there have been very rare cases of the following side effects reported following treatment with other quinolone antibiotics, which might possibly also occur during treatment with moxifloxacin:

- Raised pressure in the skull (symptoms include headache, visual problems including blurred vision, “blind” spots, double vision, loss of vision),
- Increased blood sodium levels
- Increased blood calcium levels
- A special type of reduced red blood cell count (haemolytic anaemia)

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

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

5. How to store Erelan

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 carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Erelan contains

- The active substance is moxifloxacin. Each film-coated tablet contains 400mg moxifloxacin (as hydrochloride).
- The other ingredients are: tablet core - microcrystalline cellulose (E 460), lactose monohydrate 230, croscarmellose sodium (E 468), magnesium stearate (E 470b); film-coat – hypromellose (E 464), macrogol (E 1521), titanium dioxide (E171), red iron oxide (E172).

What Erelan looks like and contents of the pack

Red, oval-shaped, biconvex film coated tablets embossed “MC” with dimensions of nucleus 17.6mm x8mm.

Tablets are packed in Al /Al blisters. Pack sizes of 5, 7, 10, 50, 70, 80 and 100 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en

Medochemie Ltd,
1-10 Constantinoupoleos street,
3011 Limassol,
Cyprus

In het register ingeschreven onder:

RVG 121751

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

| | |
|-----------|---|
| Bulgarije | ERELAN 400 mg Фильмирани таблетки |
| Cyprus | ERELAN 400mg επικαλυμμένα με λεπτό υμένιο δισκία |
| Estland | FLOXELAN |
| Litouwen | FLOXELAN 400mg plėvele dengtos tabletės |
| Malta | ERELAN 400mg film-coated tablets |
| Nederland | Erelan 400 mg filmomhulde tabletten |
| Roemenië | ERELAN 400mg comprimate filmate |
| Spanje | ERELAN 400mg comprimidos recubiertos con película |

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Deze bijsluiter is voor het laatst goedgekeurd in april 2024.