ERELAN FILM-COATED TABLETS

Moxifloxacin (400mg)

What is in this leaflet

What Erelan is used for

Erelan is used for treating the following bacterial infections when caused by bacteria which moxifloxacin is active:

- Infections of the respiratory tract: Sudden worsening of long term inflammation of the airways (chronic bronchitis), infection of the lungs (pneumonia) acquired outside the hospital, or acute infection of the sinuses
- 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
- Severe infections of the skin and associated soft tissues (e.g. major abscesses, infected burns, ulcers and bite wounds, diabetic foot infections)
- Severe infections of the abdominal cavity such as abscesses

How Erelan works

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

Before you use Erelan

- *When you must not use it*

Do not take this medicine if you:

- are allergic to moxifloxacin or any other quinolone antibiotics or ingredients of this medicine
- are pregnant or breastfeeding

-Before you start to use it

- You should not take fluoroquinolone antibacterial medicines, including Erelan, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone.
- Tell your healthcare providers if you have been diagnosed with an enlargement of "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- Tell your healthcare providers if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).
- You should not take fluoroquinolone antibacterial medicines, including Erelan, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

Warning and precautions

Talk to your doctor before taking Erelan for the first time:

- Erelan can change your heart's ECG (electrical recording of the heart), especially if you are female, or if you are elderly. If you were born with or have had any condition with abnormal heart rhythm, have salt imbalance in the blood (especially low level of potassium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a coronary heart disease, have a severe liver disease (liver cirrhosis), or you are taking other medicines that may affect your heart rhythm
- If you are taking any medicine that decreases your blood potassium levels
- If you suffer from epilepsy or a condition which makes you likely to have convulsions
- If you have myasthenia gravis (a type of muscle weakness) because taking Erelan may worsen the symptoms of your disease.
- If you have or have ever had any mental health problems
- If you have a history of tendon disease or disorder which was related to treatment with fluoroquinolone antibiotics
- If you have diabetes, consult your doctor before taking Erelan as it may cause disturbances in the blood sugar level, especially if you are elderly and treated with oral medicines or insulin to lower your blood sugar. Your doctor may monitor your blood sugar level.
- If you have severe 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 Erelan tablet is not appropriate.
- For mild to moderate infections of the female upper genital tract your doctor should prescribe another antibiotic in addition to Erelan

Children and adolescents

The efficacy of Erelan in children and adolescents has not been established. No recommendation on a posology can be made.

Pregnancy and Lactation

- Do not take Erelan if you are pregnant or breast-feeding.
- Consult your doctor if you are pregnant, planning for pregnancy or breast-feeding before using this medicine.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines obtained without a prescription:

- Medicines that affect the heart as there is an increased risk for altering your heart rhythm. Medicines that belong to the group of anti-arrhythmics (e.g. quinidine, procainamide, 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), and other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).
- Medicines that can lower your blood potassium levels (e.g. some diuretics, laxatives and enemas [high dose] or corticosteroids [anti-inflammatory drugs], amphotericin B) or cause slow heart rate because these can also increase the risk of serious heart rhythm disturbances while taking Erelan.

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- [Film-coated tablets only] Any medicine containing magnesium or aluminium such as antacids for indigestion, or any medicine containing iron or zinc, other minerals and multi-vitamins, medicine containing didasosine or medicine containing sucralfate to treat gastrointestinal disorders can reduce the action of Erelan tablets. Therefore, you should take these other medicines at least 4 hours before or 2 hours after taking Erelan tablets.
- If you are currently taking oral anti-coagulants (e.g. warfarin), your doctor may monitor your blood clotting times.
- Taking oral medicinal charcoal at the same time as Erelan tablets reduces the action of Erelan. Therefore it is recommended that these medicines are not used together.

Erelan with food and drink:
The effect of Erelan is not influenced by food including dairy products

How to use Erelan

-How much to use

The recommended dose for adult is one 400mg tablet once daily and should not be exceeded.
No adjustment of the dose is required in elderly patients, ethnic groups, in patients with impaired liver function or in patients with kidney problems

-When to use it

Erelan is for oral use. Swallow the tablet as a whole with plenty of liquid. You can take Erelan with or without food.

-How long to use it

The duration of treatment depends upon the type of infection. Unless otherwise indicated by your doctor the recommended durations of use of Erelan are:

- Sudden worsening of chronic bronchitis: 5 days
- Infection of the lungs (pneumonia) acquired outside the hospital: 10 days
- Acute infection of the sinuses: 7 days
- Mild to moderate infections of the skin and associated soft tissues: 7 days
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease): 14 days
- Severe infections of the skin and associated soft tissues:7-21 days (total treatment duration for intravenous therapy followed by oral therapy)
- Sever infections of the abdominal cavity: 5-14 days (total treatment duration for intravenous therapy followed by oral therapy)

The recommended dose and duration should not be exceeded.

If you take more Erelan than you should

If you take more than the prescribed one tablet a day, seek medical advice immediately and, if possible, take any remaining tablets, the packaging or this leaflet with you to show the doctor what you have taken.

-If you forget to use it

If you forget to take your tablet and it is:

- **8 hours or more** until your next schedules dose, you're your missed dose right away. Then take the next dose at your regular time.
- **Less than 8 hours** until your next schedules dose, do not take the missed dose. Take the next dose at your regular time.

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

While you are using it

-Things to be careful of

- If you have palpitations or irregular heart beat during treatment, 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, with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. If so, stop taking Erelan and seek medical advice immediately.
- Erelan may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases). Contact your doctor if you develop signs such as rapidly feeling unwell and/or being sick associated with yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or liver induced disease of the brain
- If you develop a skin reaction or blistering and/or peeling of the skin and/or mucosal reactions
- Erelan, may cause convulsions. If it happens, stop taking Erelan and contact the doctor immediately.
- You may develop diarrhoea during or after taking Erelan. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Erelan and consult your doctor. In this situation, you should not take medicines that stop or slow down bowel movement.
- Erelan may make your skin sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight, strong sunlight and should not use sunbed or any other UV lamp.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, inform your doctor immediately prior to continuing treatment with Erelan.
- You may experience mental health problems even when taking Erelan for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behavior such as suicide attempts. If this happens, stop taking Erelan and inform your doctor immediately.
- You may rarely experience symptoms of nerve damage such as pain, burning, tingling, numbness and/or weakness especially in the feet, legs, hands or arms. If this happens, stop taking Erelan and inform your doctor immediately to prevent the development of potentially irreversible condition.

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged disabling and potentially irreversible serious side effects

- Fluoroquinolone 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.
- Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:
  - Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.

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- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, ticking, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

- Tell your healthcare providers of you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing also an antibiotic from another class.
- 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 healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- Peripheral neuropathy
  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 healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Driving and using machines
This medicine may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision, or you might faint for a short period. If you are affected, do not drive or operate machinery.

Side effects
Like all medicines, Erelan can cause side effects, although not everyone gets them.
Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability

Common: may affect up to 1 in 10 people
- Mycotic superinfections (infections caused by fungi e.g. oral and vaginal infections caused by Candida)
- Headache, dizziness
- QT prolongation in patients with hypokalaemia (delayed electrical recovery time within the heart (shown by ECG) in patients with low blood potassium level)
- Nausea, vomiting, gastrointestinal and abdominal pain, diarrhea
- Increase in transaminases (a special liver enzyme in the blood)

Uncommon: may affect up to 1 in 100 people
- Anemia (low red blood cell count), leukopenia (low white blood cell count), neutropenia (low numbers of special white blood cells (neutrophils)), thrombocytopenia or thrombocythemia (decrease or increase of special blood cells necessary for blood clotting), prolonged prothrombin time / INR increased (decreased blood clotting)
- Allergic reaction
- Pruritus (itching), rash, urticaria (skin hives)
- Blood eosinophilia (increased specialized white blood cells (eosinophils))
- Hyperlipidemia (increased blood lipids (fats))
- Anxiety reactions, psychomotor hyperactivity/agitation (restlessness)
- Par- and Dysesthesia (tingling sensation (pins and needles) and/or numbness), taste disorders (in very rare cases ageusia (loss of taste)), confusion and disorientation, sleep disorders (predominately sleeplessness), tremor (shaking), vertigo (sensation of dizziness, spinning or falling over), somnolence (sleepiness)
- Visual disturbances including double and blurred vision
- QT prolongation (delayed electrical recovery time within the heart shown by ECG), palpitations (irregular heart beat), tachycardia (fast heart beat)
- Vasodilatation (widening of blood vessels)
- Dyspnea (difficulty in breathing) incl. asthmatic conditions
- Decreased appetite and food intake, constipation, dyspepsia (stomach upset, indigestion, heartburn), flatulence (wind), gastroenteritis (inflammation of the stomach), increased amylase (a special digestive enzyme in the blood)
- Impaired liver function, incl. LDH increase (a special liver enzyme in the blood), increase of bilirubin in the blood, increase of gamma-glutamyl-transferase and/or alkaline phosphatase in the blood (special liver enzymes in the blood)
- Arthralgia (joint pain), myalgia (muscle pain)
- Dehydration (caused by diarrhea or reduced fluid intake)
- Feeling unwell (predominantly weakness or tiredness), unspecific aches and pains such as back, chest, pelvic and extremities pains, sweating

Rare: may affect up to 1 in 1,000 people
- Abnormal thromboplastin level (special enzyme in the blood involved in blood coagulation)
- Anaphylactic / anaphylactoid reaction (severe, sudden generalised allergic reaction, e.g. difficulty in breathing, drop of blood pressure, fast pulse), allergic edema / angioedema incl. laryngeal edema (swelling incl. potentially life-threatening swelling of the airway)
- Hyperglycemia (increased blood sugar), hyperuricemia (increased blood uric acid)
- Emotional lability, depression (in very rare cases leading to self-harm, such as suicidal ideations/thoughts (desire to kill oneself), or suicide attempts), hallucinations
- Abnormal dreams
- Disturbed coordination (incl. gait disturbances, esp. due to dizziness or vertigo; in very rare cases leading to fall with injuries, esp. in elderly)
- Hypoesthesia (reduced skin sensation), smell disorders (incl. anosmia (loss of smell))
- Seizures include grand mal convulsions (loss of consciousness and violent muscle contractions)
- Disturbed attention, impaired speech, amnesia (partial or total loss of

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memory), peripheral neuropathy and polyneuropathy (troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities)
- Tinnitus (ringing/noise in the ears), hearing impairment including deafness (usually reversible)
- Ventricular tachyarrhythmias (abnormal fast heart rhythm), syncope (fainting)
- Hypertension (high blood pressure), hypotension (low blood pressure)
- Dysphagia (difficulty in swallowing), stomatitis (inflammation of the mouth), antibiotic associated colitis (severe diarrhoea containing blood and/or mucus), which in very rare circumstances, may develop into complications that are life-threatening
- Jaundice (yellowing of the whites of the eyes or skin), hepatitis (inflammation of the liver)
- Tendonitis (pain and swelling of the tendons), increased muscle tone and cramping, muscular weakness
- Impairment or failure of the kidneys (due to dehydration esp. in the elderly with pre-existing disorders of the kidneys)
- Edema (swelling of the hands, feet, ankles, lips, mouth, throat)

Very rare: may affect up to 1 in 10,000 people
- Prothrombin level increased / INR decreased (increased blood clotting) prothrombin level / INR abnormal (abnormal blood clotting)
- Anaphylactic / anaphylactoid shock (severe, sudden generalised allergic shock), potentially life-threatening
- Hypoglycemia (decreased blood sugar)
- Depersonalization (feeling of self-detachment, not being yourself), psychotic reactions (potentially leading to self-harm, such as suicidal ideations/thoughts (desire to kill oneself), or suicide attempts)
- Hyperesthesia (increase of skin sensitivity)
- Transient loss of vision
- Unspecified arrhythmias (abnormal heart rhythms), Torsade de Pointes (life-threatening irregular heart beat), cardiac arrest (stopping of heart beat)
- Fulminant hepatitis (severe inflammation of the liver) potentially leading to life-threatening liver failure (incl. fatal cases)
- Bullous skin reactions (painful blisters in the mouth/nose or at the penis/vagina), like Stevens-Johnson-Syndrome or Toxic Epidermal Necrolysis, potentially life-threatening
- Tendon rupture, arthritis (inflammation of joints), gait disturbance (caused by muscular, tendon or joint symptoms), worsening of the symptoms of myasthenia gravis

In isolated instances, some serious adverse drug reactions may be long-lasting (> 30 days) and disabling; such as tendinitis, tendon rupture, musculoskeletal disorders, and other reactions affecting the nervous system including psychiatric disorders and disturbance of senses.

The following symptoms have been observed more frequently in patients treated intravenously (followed by oral therapy):
Common: Increased gamma-glutamyl-transferase (a special liver enzyme in the blood)

Uncommon: Ventricular tachyarrhythmias (abnormal fast heart rhythm), hypotension (low blood pressure), edema (swelling of the hands, feet, ankles, lips, mouth, throat), antibiotic associated colitis (severe diarrhoea containing blood and/or mucus), which in very rare circumstances, may develop into complications that are life-threatening, Seizures incl grand mal convulsions (loss of consciousness and violent muscle contractions), hallucinations, impairment and failure of the kidneys (due to dehydration esp. in the elderly with pre-existing disorders of the kidneys).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Erelan

-Storage
- Stored the tablets below 30°C in the original packing.
- Keep this medicine out of the sight and reach of children.

-Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

-What it looks like
Red, oval-shaped, biconvex film coated tablets embossed “MC” with dimensions of nucleus 17.6mmx8mm

-Ingredients
-Active ingredient: Moxifloxacin

-Inactive ingredients
Microcrystalline cellulose (PH101), lactose monohydrate, Croscarmellose sodium, Magnesium stearate, hypromellose 2910/5, macrogol 4000, Titanium dioxide (E171), Iron oxide red (E172)

-MAL numbers:
Erelan 400mg film-coated tablets MALxxxxxxxxAZ

Manufacturer
Medochemie (Far East) Ltd. (Oral Facility), No. 40, Street 6, Vietnam Singapore Industrial Park II, Binh Duong Industry Service Urban Complex, Hoa Phu ward, Thu Dau Mot city, Vietnam

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Date of Revision
10/09/2025

Serial Number
NPRA(R2)24/147