Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Megaxin tablets
Film-coated tablets

Each tablet contains:
moxifloxacin (as hydrochloride) 400 mg

Inactive ingredients and allergens: section 2 under "Important information about some of this medicine's ingredients", and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1) What is this medicine intended for?
Megaxin is intended to treat patients above the age of 18 years for:
- Infection of the airways - including acute bacterial sinusitis.
- Worsening of chronic bronchitis. Megaxin tablets should only be used to treat these infections when other medicines intended to treat them cannot be used or the treatment with them has failed.
- Non-severe cases of pneumonia. Megaxin tablets should only be used when other medicines intended to treat this infection cannot be used.
- Skin infections.

Therapeutic group: Antibiotic of the fluoroquinolone group.

2) Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to moxifloxacin, any other quinolone antibiotic or any of the other ingredients of this medicine. For the list of inactive ingredients, see section 6 "Additional information".
- You are pregnant or breast-feeding.
- You are under 18 years of age.
- You have a history of tendon disease or tendon disorder which was related to treatment with quinolone antibiotics (see section 2 "Important information about some of this medicine's ingredients" and section 4 "Side effects").
- You were born with or have had any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of abnormal heart rhythms, or you are taking other medicines that result in abnormal ECG changes (see "Drug interactions" below). This is because Megaxin tablets may cause changes in ECG, that is a prolongation of the QT interval, i.e. delayed conduction of electrical signals.
- You have a severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Special warnings about using this medicine
Before treatment with Megaxin tablets:
You should not take fluoroquinolone/quinolone antibacterial medicines, including Megaxin tablets, if you have experienced any serious side effect in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

Before treatment with Megaxin tablets, tell your doctor if:
- Megaxin tablets may **change your cardiac 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 Megaxin tablets (see also sections "Do not use this medicine if" and "Drug interactions").
- You have previously developed **a severe skin rash or skin peeling, blistering and/or mouth ulcers** after taking moxifloxacin.
- You suffer from **epilepsy** or a condition which makes you likely to have **convulsions**, consult your doctor before taking Megaxin tablets.
- You have or have ever had any **mental health problems**, consult your doctor before taking Megaxin tablets.
- You suffer from **myasthenia gravis**, taking Megaxin tablets may worsen the symptoms of your disease. If you think you are affected, consult your doctor immediately.
- You have been diagnosed with a **dilatation or "bulge" of a large blood vessel** (aortic aneurysm or large vessel peripheral aneurysm).
- You have experienced a previous episode of **aortic dissection** (a tear in the aortic wall).
- You have been diagnosed with leaking heart valves (heart valve regurgitation).
- 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)).
- You are **diabetic** because you may experience a risk of **change in blood sugar levels** while taking moxifloxacin.
- You or any member of your family have **glucose-6-phosphate dehydrogenase (G6PD) deficiency** (a rare hereditary disease), inform your doctor, who will advise whether Megaxin tablets is suitable for you.

While taking Megaxin tablets
- 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, with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness upon standing. **If so, stop taking Megaxin tablets and seek medical advice immediately.**
- Megaxin tablets may cause a **rapid and severe inflammation of the liver**, which could lead to life-threatening liver failure (including fatal cases, see section 4 "Side effects"). Please contact your doctor before you continue the treatment if you develop signs such as rapidly feeling unwell and/or sensation of nausea associated with yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or disease of the brain caused by liver problems (symptoms of reduced liver function or a rapid and severe inflammation of the liver).
- **Serious skin reactions:** Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP) have been reported with the use of moxifloxacin.
  SJS/TEN - can appear initially as red target-like spots or circular patches, usually with central blisters. In addition, ulcers in the mouth, throat, nose, genitals and eyes (red and swollen eyes) may occur. These serious skin rashes have been usually preceded by fever and/or flu-like symptoms. These rashes can develop into 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 locations are the skin folds, back, and upper extremities.
  If you develop a serious rash or any of the other skin symptoms, stop taking moxifloxacin and contact your doctor or seek medical attention immediately.
- Quinolone antibiotics, including Megaxin tablets, may cause **convulsions**. If this happens, stop taking Megaxin tablets and contact your doctor immediately.
- **Prolonged, disabling and potentially irreversible serious side effects.**
  Fluoroquinolone/quinolone antibacterial medicines, including Megaxin tablets, 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 in the upper and lower limbs, difficulty in walking, abnormal sensations such as "pins and needles", tingling, tickling, numbness or burning (paresthesia), 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 Megaxin tablets, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment, also considering an antibiotic from another class.
- 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 Megaxin tablets and inform your doctor immediately in order to prevent the development of a potentially irreversible condition.
- You may experience **mental health problems** even when taking quinolone antibiotics, including Megaxin tablets, 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 (see section 4 "Side effects"). If you develop such reactions, stop taking Megaxin tablets and inform your doctor immediately.
- You may develop diarrhea while taking, or after taking antibiotics, including Megaxin tablets. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking Megaxin tablets immediately and consult your doctor. In this situation, you must 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 (see section 2 "Do not use this medicine if" and section 4 "Side effects"). 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 treatment with Megaxin tablets. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Megaxin tablets, contact your doctor and let the painful area rest. Avoid any unnecessary exercise, as this might increase the risk of tendon rupture.
- 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 sudden heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.
- If you are elderly with existing **kidney problems**, take care that your fluid intake is sufficient, because dehydration 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 sections "Driving and using machines" and sect ion 4 "Side effects").
- 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 (hypoglycemia), potentially leading to loss of consciousness (hypoglycemic coma) in severe cases (see section 4 "Side effects"). If you suffer from diabetes, your blood sugar level 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 must not use a sunbed or any other UV lamp while taking Megaxin tablets.
- The efficacy of moxifloxacin solution for infusion in the treatment of severe burns, infections of deep tissues and diabetic foot infections with osteomyelitis (infections of the bone marrow) has not been established.

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 use this medicine if" above).

Drug interactions
If you are taking, have recently taken or may take other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- If you are taking Megaxin tablets and other medicines that affect your heart, there is an increased risk for altering your heart rhythm. Therefore, do not take Megaxin together with the following medicines:
  - medicines that belong to the group of anti-arrhythmics (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 [at high doses] or corticosteroids [anti-inflammatory drugs], amphotericin B) or cause a slow heart rate, because these medicines may also increase the risk of serious heart rhythm disturbances while taking Megaxin tablets.
- Any medicine containing magnesium or aluminum such as antacids for indigestion, or any medicine containing iron or zinc, medicine containing didanosine or medicine containing sucralfate to treat gastrointestinal disorders may reduce the action of Megaxin tablets. Therefore, take Megaxin tablets 6 hours before or after taking the other medicine.
- Taking oral medicinal charcoal at the same time as Megaxin tablets reduces the action of Megaxin tablets. Therefore, it is recommended not to use these medicines together.
- If you are currently taking oral anticoagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting times.

Using this medicine and food
The effect of Megaxin tablets is not influenced by food, including dairy products.

Pregnancy, breastfeeding and fertility
Do not take Megaxin tablets if you are pregnant or breastfeeding.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.
Animal studies do not indicate that your fertility will be impaired by taking this medicine.

Driving and using machines
Megaxin tablets 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 in this way, do not drive or operate machines.

Important information about some of this medicine's ingredients
This medicine contains lactose and sodium.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Megaxin tablets.
This medicine contains less than 1 millimole sodium (23 milligrams) per film-coated tablet, that is to say essentially "sodium-free".

3) How to use this medicine?
Always use this medicine according to the instructions of your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually one tablet per day. Take the tablet at approximately the same time each day.

Do not exceed the recommended dose.

Manner of intake
The tablets are for oral use. There is no information regarding crushing/splitting/chewing.
Swallow the tablet as a whole (to mask the bitter taste) with or without food. Drink plenty of liquid while taking Megaxin tablets.

No adjustment of the dose is required in elderly patients, patients with a low bodyweight or in patients with kidney problems.

The duration of treatment depends upon the type of infection. 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 this medicine too soon your infection may not be completely cured, the infection may return or your condition may get worse, and you may also create resistance to the antibiotic.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you forget to take the medicine at the scheduled time, take a dose as soon as you remember on the same day. If you do not take your tablet on that day, take your normal dose (one tablet) on the next day. Do not take more than one dose of Megaxin tablets in one day. If you are unsure about how to take the medicine, consult your doctor or pharmacist.

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

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) Side effects
Like with all medicines, using Megaxin tablets may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The **most serious side effects** observed during the treatment with Megaxin tablets are listed below.

Stop taking Megaxin tablets and contact your doctor immediately, as you may need urgent medical advice, 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 (acute) inflammation of the liver potentially leading to life-threating liver failure (a very rare side effect, fatal cases have been observed))
- serious skin rashes including Stevens-Johnson syndrome (STS) and toxic epidermal necrolysis (TEN). These can appear as red target-like macules or circular patches, usually with central blisters, skin peeling, ulcers in the 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 generalized exanthematous pustulosis - AGEP) (the frequency of this side effect is not known)
- a syndrome associated with impaired water excretion and low levels of sodium (SIADH) (a very rare side effect)
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycemic coma) (a 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) (a very rare side effect)
- a severe, sudden allergic reaction, including, very rarely, a life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse) (a rare side effect)
- swelling, including swelling of the airways (a rare side effect, potentially life-threatening)
- convulsions (a rare side effect)
- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (a rare side effect)
- depression (in very rare cases leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (a rare side effect)
- insanity (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (a very rare side effect)
- severe diarrhea containing blood and/or mucus (antibiotic associated colitis, including 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) (a rare side effect) or a tendon rupture (a very rare side effect)
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high body temperature or have dark urine. These effects may be caused by an abnormal muscle breakdown, which can be life-threatening and lead to kidney problems (a condition called rhabdomyolysis) (the frequency of this side effect is not known)

In addition, if you notice:
- transient loss of vision (a very rare side effect),
- discomfort or pain in the eyes, especially due to light exposure (a very rare to 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 Megaxin tablets (very rare side effects), **tell your doctor immediately that you have taken Megaxin tablets and do not resume the treatment.**

Worsening of myasthenia gravis symptoms 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 (a rare or very rare side effect), **inform your doctor immediately.**

If you are elderly with existing kidney problems and you notice a 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 Megaxin tablets are listed below by frequencies:

Common side effects (may affect up to 1 in 10 users):
- nausea
- diarrhea
- dizziness
- stomach and abdominal ache
- vomiting
- headache
- increase in 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 side effects (may affect up to 1 in 100 users):
- rash
- abdominal discomfort (indigestion/heartburn)
- changes in taste (in very rare cases loss of taste)
- sleep problems (predominantly sleeplessness)
- increase in 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 (including increase in a special liver enzyme in the blood (LDH))
- decreased appetite and food intake
- low white blood cell count
- aches and pain such as pain in the back, chest, pelvis and extremities
- increase in special blood cells necessary for blood clotting
- sweating
- increased specialized white blood cells (eosinophils)
- anxiety
- feeling unwell (predominantly weakness or tiredness)
- shaking
- joint pain
- palpitations
- irregular and fast heart beat
- difficulty in breathing, including asthmatic conditions
- increase in 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 in special blood cells necessary for blood clotting
- vision disturbances, including double and blurred vision
- decreased blood clotting
- increased blood lipids
- low red blood cell count
- muscle pain
- allergic reaction
- increase in bilirubin in the blood
- inflammation of the stomach
- dehydration
- severe heart rhythm abnormalities
- dry skin
- angina pectoris

Rare side effects (may affect up to 1 in 1,000 users):
- muscle twitching
- muscle cramp
- hallucinations
- high blood pressure
- swelling (of the hands, feet, ankles, lips, mouth, throat)
- low blood pressure
- kidney impairment (including 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
- concentration disorder
- difficulty in swallowing
- changes in smell (including loss of smell)
- balance disorder and poor coordination (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 side effects (may affect up to 1 in 10,000 users):
- a drop in the number of red and white blood cells and platelets (pancytopenia)
- inflammation of joints
- abnormal heart rhythms
- increased skin sensitivity
- a feeling of self-detachment (not being yourself)
- increased blood clotting
- muscle rigidity
- a significant decrease in special white blood cells (agranulocytosis)

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 preexisting risk factors.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones (see section 2, 'Special warnings about using this medicine').

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 Megaxin tablets: raised pressure in the skull (symptoms include headache, vision 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 (hemolytic anemia), increased sensitivity of the skin to sunlight or UV light.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.
Contact your doctor if you feel that your condition does not improve while taking Megaxin tablets.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5) How to store the medicine?
- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C in the original package to protect from moisture.
- 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) Additional information
- In addition to the active ingredient, this medicine also contains:
  Cellulose microcrystalline, lactose monohydrate, croscarmellose sodium, magnesium stearate, hypromellose 15 cP, macrogol 4000, titanium dioxide, ferric oxide red
- What the medicine looks like and contents of the pack:
  Megaxin tablets is a dull red, film-coated, oblong tablet marked with "BAYER" on one side and "M400" on the other side.
  The tablets are supplied in blisters in packs of 5, 7 and 10 tablets.
  Not all pack sizes may be marketed.
- **Registration holder's name and address:** Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- **Manufacturer's name and address:** Bayer AG, Leverkusen, Germany.
- Revised in March 2022 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 117 77 29884 01/02

DOR-MEG-tabs-0822-10