PATIENT INFORMATION LEAFLET

POL-MOXİ 400 mg/250 mL Solution for I.V. Infusion
It is administered into a vein.
Sterile

• ***Active ingredient:*** Each 250 ml POL-MOXİ bag contains 400 mg moxifloxacin (as hydrochloride).

• ***Excipients:*** Sodium chloride, hydrochloric acid solution, 0,1 N sodium hydroxide solution, water for injection

Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.

• Keep this PATIENT INFORMATION LEAFLET. You may need to re-read it later.

• In case you have additional questions, please consult your doctor or pharmacist.

• This drug is prescribed personally for you, do not give to others.

• During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.

• Please follow these instructions strictly. Do not use dosages ***higher or lower*** *than the dosage recommended to you.*

The following topics are included in this Patient Information Leaflet:

1. What is POL-MOXİ and what is it used for?

- POL-MOXİ infusion solution to be injected dropwise into a vein (infusion) are available in the form of ready solution. Each bag contains 400 mg of active substance (moxifloxacin).
- POL-MOXİ contains the active substance moxifloxacin, which belongs to a group of antibiotics called fluoroquinolones. POL-MOXİ works by killing different kinds of bacterias that cause infections if they are caused by bacteria that are susceptible to moxifloxacin.
- POL-MOXİ is available in 250 mililiter PP bags.
- POL-MOXİ is indicated for treatment of the following infectious diseases caused by susceptible microorganisms (microbes):
  - Infection of the lungs (pneumonia) acquired outside the hospital

- Skin and soft tissue infections (uncomplicated) that do not accompany another picture

- Group of the drugs including POL-MOXİ (fluoroquinolones), should not be used for acute bacterial exacerbation of chronic bronchitis (re-aggravation of the persistent inflammation of the membranes of the bronchial tubes in the lung) due to the risk of serious adverse effects in the presence of alternative treatment options.
- POL-MOXİ can only be used in the treatment of infections that have been proven to be susceptible to susceptible bacteria or that have serious suspicion.

2. Before you are given POL-MOXİ

- The group of antibiotics called moxifloxacin and moxifloxacin, the active ingredient of POL-MOXİ, can cause disabling and irreversible side effects as follows:
- Tendonitis (tendon inflammation) and tendon (ligaments connecting muscles to bones)
- Peripheral neuropathy (nerve damage)
- Central nervous system effects (hallucinations (seeing, hearing or feeling), anxiety (anxiety), depression, suicidal tendency, insomnia (sleep disorders), severe headache and confusion (sudden confusion))
- In patients with any of these reactions, use of POL-MOXİ should be discontinued immediately and fluoroquinolone should be avoided.
- Fluoroquinolones, including POL-MOXİ, may exacerbate muscle weakness in patients with myasthenia gravis (a disease that leads to muscle weakness). Use of POL-MOXİ should be avoided in patients with a known history of myasthenia gravis.
- Since the fluoroquinolone group drugs, including POL-MOXİ, are known to be associated with serious side effects, the following indications may be used if there are no other alternatives.
- Acute bacterial exacerbation of chronic bronchitis (re-exacerbation of persistent inflammation of the membranes of the bronchial tubes in the lung)

Fluoroquinolones, including POL-MOXİ, have been associated with serious side effects that can cause disability and are potentially irreversible. Common side effects include musculoskeletal and peripheral nervous system (tendonitis) and tendon rupture, tendon swelling or inflammation, tingling or numbness, numbness of arms and legs, muscle pain, muscle weakness, joint pain , arthralgia (joint pain), myalgia (muscle pain), peripheral neuropathy (damage to the nerves), effects of the central nervous system (hallucination (seeing things, hearing or feeling), anxiety (anxiety), depression, suicidal tendency, insomnia, severe headache and confusion (sudden confusion) (see “What are the possible side effects? section) These side effects can occur within hours or weeks after starting POL-MOXİ or patients without pre-existing risk factors experienced these side effects. POL-MOXİ should be discontinued immediately if symptoms or signs occur. Furthermore, the use of fluoroquinolones, including POL-MOXİ, should be avoided in patients experiencing any of these serious side effects associated with fluoroquinolones.

DO NOT USE POL-MOXİ UNDER THE FOLLOWING CONDITIONS

If,

- If you are allergic to moxifloxacin, other antibiotics from quinolone group or one of the excipients in this drug product,
- If you are pregnant,
- If you are breastfeeding your baby,
- If you are under 18,
- If you have suffered damage to the tendon (extensions that connect the muscles to the bone) associated with quinolone therapy, an antibiotic group (see Use Pol-Moxi Carefully under the Following Conditions and 4. Possible side effects?),
- If you have a congenital or acquired abnormal heart rhythm disorder (seen on your ECG),
- If you have a lack of salt (sodium and potassium) in your blood (electrolyte disturbances, especially uncorrected hypokalemia),
- If your heart rate is low (bradycardia),
- If you have a weak heart (heart failure),
- If you have a previous heart rhythm disorder (symptomatic arrhythmia),
- You are taking moxifloxacin concurrently with other medications that cause deterioration of the heart radiograph (see section Concomitant use with other medicines). Because POL-MOXİ can cause QT interval prolongation on cardiac X-ray (ECG). For example; Delayed transmission of electrical signals.
- You have severe liver disease (Child Pugh C) or liver enzymes (transaminases) that are higher than 5 times the upper normal limit.

USE POL-MOXİ CAREFULLY UNDER THE FOLLOWING CONDITIONS

If you are using POL-MOXİ for the first time, talk to your doctor before using it.

• POL-MOXİ can alter ECG especially in women and the elderly. If you have recently taken medication to lower your blood potassium levels, consult your physician before using POL-MOXİ (see section Do Not Use Pol-Moxi under the Following Conditions and Taking other medicines).

• If you have epilepsy or if you are in a condition that leads to convulsions, talk to your doctor before using POL-MOXİ.

• If you have or have had a mental illness, talk to your doctor before using POL-MOXİ.

• Aggravation of myasthenia gravis (a muscle weakness): fluoroquinolones such as POL-MOXİ can cause worsening of myasthenia gravis symptoms such as muscle weakness and respiratory problems. If you have Myasthenia Gravis, you should avoid taking this medicine.

• If your family has glucose-6-phosphate dehydrogenase (blood sugar) deficiency (a rare hereditary disease), inform your doctor about this and decide whether POL-MOXİ is suitable for you.

• POL-MOXİ should only be administered intravenously, not intravenously.

• Inform your doctor immediately if you have palpitations or irregular heartbeat during treatment. Your doctor may want to take your heart graph (ECG) to measure your heart rhythm.

• The risk of heart problems may increase due to the rate of perfusion through the vein and the increase in dose.
• Very rarely and sometimes after the first application, sudden and severe hypersensitivity reactions (anaphylactic reactions / shock) may occur, chest tightness, feeling dizzy, feeling sick or weak, dizziness when standing up. In this case, use of POL-MOXİ should be discontinued and your doctor informed immediately.
• POL-MOXİ can cause rapid and severe liver inflammation, which can lead to life-threatening liver failure (including fatal cases, see Chapter "4. What are the possible side effects?"). If you suddenly feel bad and / or have nausea and also have yellowing of your eyes, dark urine, skin itching, bleeding tendency, or liver-related brain disease (signs of decreased liver function or rapid and severe liver inflammation), please do not take another tablet. Please contact your doctor first.
• If you experience a skin reaction or blistering / peeling of the skin and / or mucosal reactions (see Section "4. Possible side effects?"), Contact your doctor immediately before continuing treatment.
• Quinolone antibiotics, including POL-MOXİ, can cause convulsions. If this occurs, treatment with POL-MOXİ should not be continued. You may experience signs of nerve damage (neuropathy), such as pain, burning, tingling, numbness and / or weakness, especially in the feet and legs or hands. In such a case, inform your doctor immediately before proceeding with POL-MOXİ.
• When taking fluoroquinolone antibiotics, including POL-MOXİ, you may experience mental health problems even if you are taking them for the first time. In very rare cases, depression or mental health problems have led to suicidal thoughts and self-injurious behavior, such as attempted suicide (see section "4.Possible side effects?"). If any such reactions occur, stop taking POL-MOXİ and inform your doctor immediately.
• Diarrhea may occur during or after antibiotic use, including POL-MOXİ. If this becomes serious and persistent, or if you find that your stool contains blood or mucus, stop taking POL-MOXİ immediately and consult your physician. Do not take drugs that stop or slow down bowel movements
• Even within 48 hours of initiation of POL-MOXİ treatment, it may cause pain and inflammation of your tendons, which may persist for up to several months after stopping POL-MOXİ treatment. The risk of inflammation and tearing of the tendons increases if you are older or are taking concurrent corticosteroids. Stop taking POL-MOXİ at the first sign of any pain or inflammation, rest the affected joints and consult your physician immediately. Avoid unnecessary exercise as it may increase the risk of tendon rupture (see Do Not Use Pol-Moxi under the Following Conditions and "4. Possible side effects" sections).
• If you are older and have kidney problems, take care to consume enough fluids when taking POL-MOXİ, as this may increase the risk of renal failure in case of dehydration.
• If your vision deteriorates or your eyes appear to have a problem, consult an ophthalmologist immediately (see chapter 4, What are the possible side effects?). Stop taking the medicine immediately and consult your doctor.
• Do not take drugs that stop or slow down bowel movements.
• Fluoroquinolone antibiotics can cause blood sugar disorders, such as when blood sugar falls below normal (hypoglycemia) and blood sugar rises above normal (hyperglycemia). Blood

sugar disorders in patients treated with POL-MOXİ predominantly occurred in elderly patients receiving concomitant treatment with oral antidiabetic drugs (such as sulfonylurea) or insulin, which lower blood sugar. If you have diabetes, your blood sugar should be monitored carefully (see section “4. Possible side effects?”).
• Quinolone antibiotics can make your skin more sensitive to sunlight or UV light. When taking POL-MOXİ, you should avoid prolonged exposure to strong sunlight and do not use a solarium or any other UV lamp. There is limited experience with the use of POL-MOXİ sequentially by intravenous / oral administration for the treatment of pneumonia acquired outside the hospital.
• The effectiveness of POL-MOXİ has not been demonstrated in the treatment of severe burns, deep tissue infections, osteomyelitis (bone marrow infections) and associated diabetic foot infections.

Use POL-MOXİ with caution:
• If a large blood vessel has been diagnosed with dilation or “swelling” (aortic aneurysm or large vessel peripheral aneurysm),
• If you have had a previous aortic dissection attack (rupture of the aortic wall),
• If your family history includes aortic aneurysm or aortic dissection, or if you have conditions that predispose to other risk factors (eg Marfan syndrome or vascular Ehlers-Danlos syndrome, or connective tissue diseases such as Takayasu's arteritis, giant cell arteritis, Behçet's disease, high blood pressure or known atherosclerosis).
If you experience sudden, severe pain in your abdomen, chest or back, seek immediate medical attention.
Please consult your physician if these warnings apply to you, even at any time in the past.

Use of POL-MOXİ with foods and drinks
POL-MOXİ is not affected by food, including dairy products.

Pregnancy
Consult your doctor or pharmacist before using this drug.

POL-MOXİ must not be used on pregnancy.

In case you become aware that you are pregnant during treatment, immediately consult your doctor or pharmacist.

Lactation
Consult your doctor or pharmacist before using this drug.

POL-MOXİ must not be used in lactating mothers.

Driving and Using Machines

POL-MOXİ can cause dizziness or dizziness, sudden and temporary loss of vision, or short-term self-sufficiency. If this is the case, you should not drive or use machines during POL-MOXİ treatment.

Important information about some excipients contained in POL-MOXİ
A POL-MOXİ bag (250 ml) contains 34 mmol sodium. This should be considered for patients on a controlled sodium diet.

Taking with other medicines
Tell your doctor or pharmacist if you are taking any other medicines beside POL-MOXİ.
For POL-MOXİ, be aware of the following:
If you are using POL-MOXİ and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, do not use POL-MOXİ 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 imipramine, amitriptyline, doxepin, clomipramine, nortriptyline, opipramol, amoxapine, tianeptine),
- 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 [large 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 using POL-MOXİ.
- If you are currently taking oral anti-coagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting times.

If you are currently using any prescribed drug or OTC, or if you have used them recently, please inform your doctor or pharmacist about these.

3. How POL-MOXİ will be given?
Instructions for proper use and dosage/application intervals:
Your doctor or health professional will decide on the duration of your treatment with drug.

Route and method of administration:
POL-MOXİ is for intravenous use. Your doctor should ensure that the infusion is given at a constant flow over 60 minutes. The recommended daily dose for adults is a vial.

Different age groups:
Pediatric use:

This medicine must not be administered 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 POL-MOXİ).*

Geriatric use:
POL-MOXİ dosage adjustment is not necessary for the elderly.

Special Conditions of Use
Renal impairment:
Elderly patients with renal impairment should pay attention to adequate fluid intake because dehydration may increase the risk of renal failure.

Hepatic impairment
No dose adjustment is required in patients with hepatic dysfunction.

If you have an impression that the effect of POL-MOXİ is too strong or too weak, consult your doctor or pharmacist.

If you had used POL-MOXİ in an amount more than you should:
If you think you are using more POL-MOXİ than you should, consult your doctor immediately.

Consult a doctor or a pharmacist if you had used POL-MOXİ in an amount more than you should.

In case you forget to take POL-MOXİ:
Do not take double dose to balance missed dose.

If you think you have missed the dose of POL-MOXİ, consult your doctor immediately.

Possible side effects when treatment with POL-MOXİ is concluded

Your infection may not have been completely cured after cessation of this medication. If you wish to discontinue treatment with the POL-MOXİ infusion solution or moxifloxacin tablet before the end of your treatment, consult your doctor.
If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
As with all medicines, this medicine can cause side effects, although not everyone is seen.
Like all drugs, POL-MOXİ also can cause adverse effects in individuals who are hypersensitive against any of the ingredients.

Very common: It can be seen in at least 1 in 10 patients.
Common: Less than one in 10 patients, but more than one in 100 patients.
Uncommon: less than one in 100 patients, but more than one in 1,000 patients.
Rarely: Less than one in 1,000 patients may be seen.
Very rare: Less than one in 10,000 patients can be seen.
Unknown frequency: It can be seen in too few patients to be determined by the available data.

Stop using POL-MOXİ and notify your doctor IMMEDIATELY or contact the emergency department of your nearest hospital:
- Abnormally fast heart rhythm (rare side effect),
- Suddenly feeling bad or jaundice in the white part of the eyes, dark urine, skin itching, bleeding tendency or thought disorder or wakefulness (these may be signs and symptoms of potentially life-threatening inflammation in the liver.) (Very rare side effects, fatal situations have been observed.)
- Changes in the skin and mucous membranes (Stevens-Johnson syndrome or toxic epidermal necrolysis), such as painful blisters in the mouth / nose or penis / vagina (very rare side effects, potentially life-threatening)
- Inflammation of the blood vessels (symptoms on your skin, usually on the lower leg, red spots or effects such as joint pain) (very rare side effect)
- Severe, generalized (common) allergic reaction, including very rarely life-threatening shock (eg difficulty in breathing, drop in blood pressure, rapid pulse) (rare side effect)
- Swelling, including swelling of the respiratory tract (rare side effects, potentially life-threatening)
- Transfers (convulsions) (rare side effects)
- Nervous system related problems such as pain, burning, tingling, numbness and / or weakness of the extremities (rare side effects)
- Depression (rarely causes self-harm such as suicidal ideation or attempted suicide) (rare side effect)
- Madness (potentially causing self-harm, such as suicidal ideation or attempted suicide) (very rare side effects)
- Serious diarrhea involving blood and / or mucus (pseudomembranous colitis, including antibiotic-associated colitis); it can rarely cause life-threatening complications. (rare side effect)
- Pain and swelling of tendons (tendonitis) (rare side effect) or tendon rupture (rupture) (very rare side effect)

In addition, if you experience temporary vision loss (very rare side effects), consult an ophthalmologist immediately.

If you have experienced life-threatening irregular heartbeats (Torsade de Pointes) or cardiac arrest during the use of POL-MOXİ (very rare side effects), immediately tell your doctor following your treatment that you are using POL-MOXİ and do not start treatment again.

Very rarely, myasthenia gravis (a disease causing muscle weakness) symptoms have been observed to worsen. If this occurs, consult your doctor immediately.

If you have diabetes (diabetes) and you feel your blood sugar rises or falls (rare or very rare), tell your doctor immediately.
If you are an elderly patient with kidney problems and you notice decreased urine volume, swelling of your legs, fatigue, nausea, drowsiness, shortness of breath, or confusion in your feet and ankles, consult your doctor immediately.

These are all very serious side effects. If you have one of these, you have a serious allergy to POL-MOXİ. You may need immediate medical attention or hospitalization.

Possible side effects of POL-MOXİ are as follows:

Common
- Headache
- Dizziness
- Change of the heart rhythm (ECG) in patients with low blood potassium level
- Nausea
- Diarrhea
- Vomiting
- Stomach-intestine and abdominal pain
- Infections caused by resistant bacteria or fungi, for example; Oral and vaginal infections caused by Candida
- Pain or inflammation at the injection site (inflammation)

Uncommon
- Redness
- Stomach discomfort (indigestion / heartburn)
- Taste disturbance (very rarely loss of this sense)
- Sleep disorders (predominantly insomnia)
- Increased of a special liver enzyme in the blood (gamma-glutamyl-transferase and / or alkaline phosphatase)
- Reduction in white blood cells (leukocytes, neutrophils)
- Constipation
- Itching
- Sensation of dizziness (rolling or falling)
- Sleepiness
- Gas
- Changes in heart radiography (ECG)
- Liver dysfunction (including increased LDH specific liver enzyme)
- Decreased appetite and eating
- Decrease in the number of white blood cells

- Body aches such as back, chest, pelvic and arm-leg (extremity) pain
- Increase in the number of specific blood cells required for blood clotting
- Sweating
- Increase in specific white blood cells (eosinophils)
- Irritability (anxiety)
- Feeling bad (usually weakness or fatigue)
- Shaking
-Joint pain
- Palpitations
- Irregular and fast heartbeat
- Difficult breathing involving asthma conditions
- An increase in the blood of a special digestive enzyme called amylase
- Unrest, anxiety
- Tingling sensation (pins and needles) and / or numbness
- Hives
- Expansion of blood vessels
- Confusion, not knowing where it is (confusion and disorientation)
- Reduction of specific cells required for blood clotting
- Visual disturbances including double and blurred vision
- Reduction in blood clotting
- Lipid (fat) increase in blood
- Reduction in red blood cells (anemia)
- Muscle pain
- Allergic reaction
- Bilurubin increase in blood
- Vascular inflammation
- Gastroenteritis
- Sweating (dehydration)
- Severe heart rhythm abnormalities
- Drying of the skin
- Chest pain (angina pectoris)

Rare

- Muscle twiching
- Muscle cramp
- See,hear or feel things are not exist (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 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

- 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)

The following symptoms have been observed more frequently in patients treated intravenously:

Common

- Increase of a special liver enzyme in the blood (gamma-glutamyl-transferase)

Uncommon

- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis) which in very rare circumstances, may develop into complications that are life-threatening
- Abnormal fast heart rhythm
- See,hear or feel things are not exist (hallucination)
- Low blood pressure
- Kidney impairment (incl. increase in special kidney laboratory test results like urea and creatinine)
- Kidney failure
- Swelling (of the hands, feet, ankles, lips, mouth, throat)
- Convulsions

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:

- Decreased blood sodium levels

- Increased blood calcium levels,
- A special type of reduced red blood cell count (haemolytic anaemia)
- Muscle reactions with muscle cell damage
- Increased sensitivity of the skin to sunlight or UV light.

In case you encounter any adverse effects not mentioned in this PATIENT INFORMATION LEAFLET, please inform your doctor or pharmacists.

5. How to store POL-MOXİ

Keep POL-MOXİ in places out of sight and reach of children and within packaging.
Please store it at room temperature under 25°C.
At temperatures below 15 ° C, at room temperature (15 ° C - 25 ° C) redissolution precipitation may occur. Therefore, it is not recommended to store *POL-MOXİ* in the refrigerator.
Store in original packaging.
Use according to the expiry date.
Do not use POL-MOXİ after the expiry date shown on the outer packaging.
If you notice any irregularities in the product and/or its packaging, do not use POL-MOXİ.

Marketing Authorisation Holder & Manufacturer:
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These patient information leaflet were approved on 28.06.2019.

THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO WILL APPLY THIS MEDICINE.

POSOLOGY AND APPLICATION METHOD

Adults:

Posology:

For the above indications, Pol-Moxi is administered once a day and this dose should not be exceeded.

The duration of treatment should be determined by the severity of the indication or the clinical response. The following general recommendations are made for the treatment of upper and lower respiratory infections:

In clinically indicated cases, treatment can be started with intravenous administration and continued with oral film-coated tablet administration.

Acute exacerbation in chronic bronchitis: 5 days

Community-acquired pneumonia: Recommended treatment duration for sequential administration (oral administration following intravenous administration): 7-14 days

Uncomplicated skin and soft tissue infections: 7 days

Sequential treatment time for complicated skin and soft tissue infections (oral administration following intravenous administration): 7-21 days.

Sequential treatment for complicated intraabdominal infections (oral administration following intravenous administration): 5-14 days.

The duration of treatment should not be exceeded for the indication being treated. In clinical studies (complicated skin and soft tissue infections), POL-MOXİ has been investigated for up to 21 days of treatment.

Route of administration:

For intravenous use; constant infusion over 60 minutes.

If medically indicated the solution for infusion can be administered via a T-tube, together with compatible infusion solutions.

The following solutions has been shown to compatible with POL-MOXİ at room temperature for 24 hours stable.

Water for injection
0.9% sodium chloride
1 M sodium chloride
5% glucose
10% glucose
40% glucose
20% xylitol
Ringer solution

Lactated ringer solution

POL-MOXİ be given with another drug, two drugs should be administered separately.

Only clear solution should be used.

Special populations
Renal/hepatic impairment
No adjustment of dosage is required in patients with mild to severely impaired renal function (included creatinine clearance ≤ 30 mL/min/l.73m2) or in patients on chronic dialysis i.e. haemodialysis and continuous ambulatory peritoneal dialysis.

There is insufficient data in patients with impaired liver function (see section 4.3).

Paediatric population:
Efficacy and safety of moxifloxacin in children and adolescents have not been established (see section 4.3).

Geriatric population:
No adjustment of dosage is required in the elderly.

Others:

No adjustment of dosage is required in the ethnic groups.

POL-MOXİ should not be used intraarterially.

OVERDOSE
Only limited data on overdose are available. Healthy volunteers were administered single doses up to 1200 mg for 10 days and repeated doses of 600 mg of moxifloxacin without any significant adverse effects. In case of overdose, appropriate supportive treatment, as required by the patient's clinical condition, with ECG measurements is recommended.

INCOMPATIBILITIES
The following infusion solutions have been shown to be incompatible with POL-MOXİ.

The following solutions are incompatible with POL-MOXİ:
- Sodium chloride 10% solutions
- Sodium chloride 20% solutions
- Sodium bicarbonate 4.2% solutions
- Sodium bicarbonate 8.4% solutions