PATIENT INFORMATION LEAFLET

MULTIFLEX MOXIFLEX 400 mg/250 mL I.V. Solution for Infusion

Sterile

Administered intravenously.

- ***Drug substance:*** 1 bag of 250 ml contains 400 mg moxifloxacin (as hydrochloride).
- ***Excipients:*** sodium chloride, hydrochloric acid, sodium hydroxide, water for injection.

Read all of this LEAFLET carefully before you start using 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.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use high or low doses other than the recommended dosage.*

What is in this leaflet:

1. What MULTIFLEX MOXFLEX is and what it is used for?

- The MULTIFLEX MOXIFLEX infusion solution is available in the form of a solution ready to be injected into the vein dropwise. Each drug bag contains 400 mg of active substance (moxifloxacin).
- MULTIFLEX MOXIFLEX active ingredient moxifloxacin is a fluoroquinolone group antibiotic.

It acts by killing different types of bacteria that cause infections.

MULTIFLEX MOXIFLEX is available in 250 ml PP bag with two outputs with protective Al overpouch.

- MULTIFLEX MOXIFLEX is used in the treatment of the following infectious diseases caused by susceptible microorganisms (microbes):
  - Out-of-hospital pulmonary infection (community-acquired pneumonia)

- (Uncomplicated) skin and soft tissue infections without any other condition,

- The drug group (including fluoroquinolones), including MOXİFLEX, 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.
- MULTIFLEX MOXIFLEX 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. What you need to know before you use MULTIFLEX MOXIFLEX

- The group of antibiotics called moxifloxacin and moxifloxacin, the active ingredient of MOXIFLEX, can cause disabling and irreversible side effects as follows:
  - o Tendonitis (tendon inflammation) and tendon (ligaments connecting muscles to bones)
  - o Peripheral neuropathy (nerve damage)
  - o Central nervous system effects (hallucinations (seeing, hearing or feeling), anxiety (anxiety), depression, suicidal tendency, insomnia (sleep disturbances), severe headache and confusion (sudden confusion)

  In patients with any of these reactions, use of MULTIFLEX MOXİFLEX should be discontinued immediately and fluoroquinolone should be avoided.
- Fluoroquinolones, including MULTIFLEX MOXİFLEX, may exacerbate muscle weakness in patients with myasthenia gravis (a disease that leads to muscle weakness). Use of MOXİFLEX should be avoided in patients with a known history of myasthenia gravis.
- Since the fluoroquinolone group drugs, including MULTIFLEX MOXİFLEX, are known to be associated with serious side effects, the following indications may be used if there are no other alternatives.
  - o Acute bacterial exacerbation of chronic bronchitis (re-exacerbation of persistent inflammation of the membranes of the bronchial tubes in the lung)

Fluoroquinolones, including MULTIFLEX MOXİFLEX, 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, swelling or inflammation of tendons, 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 (see "4. Possible side effects") These side effects can occur within hours or weeks of starting MULTIFLEX MOXİFLEX. or patients without pre-existing risk factors have experienced these side effects. MULTIFLEX MOXİFLEX should be discontinued immediately if the first signs or symptoms occur. Furthermore, the use of fluoroquinolones, including MULTIFLEX MOXİFLEX, should be avoided in patients experiencing any of these serious side effects associated with fluoroquinolones.

DO NOT USE MULTIFLEX MOXİFLEX if you;

- If you are allergic to the active substance moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breast-feeding.
- If you are under 18 years of age.
- If you have a history of tendon disease or disorder which was related to treatment with quinolone antibiotics (see sections *Warnings and precautions* and *4. Possible side effects*).
- If you were born with or have had any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart).
- If you have salt imbalance in the blood (especially low levels of potassium or magnesium in the blood).
- If you have a very slow heart rhythm (called 'bradycardia').
- If you have a weak heart (heart failure).
- If you have a history of abnormal heart rhythms.
- If you are taking other medicines that result in abnormal ECG changes (see section *Other medicines and MULTIFLEX MOXİFLEX*). This is because MULTIFLEX MOXİFLEX can cause changes on the ECG, which is a prolongation of the QT-interval i.e. delayed conduction of electrical signals.
- If you have a severe liver disease or liver enzymes (transaminases) that are higher than 5 times the upper normal limit.

USE MULTIFLEX MOXİFLEX CAREFULLY if you;

- If using MULTIFLEX MOXİFLEX for the first time, talk to your doctor before using it.
- MULTIFLEX MOXİFLEX can alter the ECG especially in women and the elderly. If you have recently taken medication to lower your blood potassium level, consult your

doctor before using MULTIFLEX MOXİFLEX (see section Do not use MULTIFLEX MOXİFLEX and use with other medicines).

- If you are suffering from epilepsy or are in a condition that leads to convulsions, talk to your doctor before using MULTIFLEX MOXİFLEX.
- If you have or have had a mental illness, talk to your doctor before using MOXİFLEX.
- Aggravation of myasthenia gravis (a disease that causes muscle weakness): fluoroquinolones such as MULTIFLEX MOXİFLEX 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 MULTIFLEX MOXİFLEX is suitable for you.
- MULTIFLEX MOXİFLEX 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, MULTIFLEX MOXİFLEX should be discontinued and your doctor informed immediately.
- MULTIFLEX MOXİFLEX can cause rapid and severe liver inflammation that 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 MULTIFLEX MOXİFLEX, can cause convulsions. If this occurs, MULTIFLEX MOXİFLEX should not be discontinued.

- 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 MULTIFLEX MOXİFLEX.
- When taking fluoroquinolone antibiotics, including MULTIFLEX MOXİFLEX, 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 Chapter "4. What are the possible side effects?"). If such reactions occur, stop taking MOXİFLEX and inform your doctor immediately.
- Diarrhea may occur during or after antibiotic use, including MULTIFLEX MOXİFLEX. If this becomes serious and persistent, or if you find that your stool contains blood or mucus, stop taking MULTIFLEX MOXİFLEX immediately and consult your doctor. Do not take drugs that stop or slow down bowel movements.
- Even within 48 hours after initiation of MULTIFLEX MOXİFLEX treatment, it may cause pain and inflammation of your tendons, which may persist for up to several months after stopping MULTIFLEX MOXİFLEX treatment. The risk of inflammation and tearing of the tendons increases if you are older or are taking concurrent corticosteroids. Stop taking MULTIFLEX MOXİFLEX at the first sign of any pain or inflammation, rest the affected joints and consult your doctor immediately. Avoid unnecessary exercise as it may increase the risk of tendon rupture (see "DO NOT USE MULTIFLEX MOXİFLEX" and "4. Possible side effects?").
- If you are older and have kidney problems, be sure to consume enough fluids when taking MULTIFLEX MOXİFLEX, 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, 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 MULTIFLEX MOXİFLEX predominantly occurred in elderly patients receiving concomitant treatment with oral anti-diabetic drugs (such as sulfonylurea) or insulin that lower blood sugar. If you have diabetes, your blood sugar should be monitored carefully (see section

"4. What are the possible side effects?").

- Quinolone antibiotics can make your skin more sensitive to sunlight or UV light. When taking MULTIFLEX MOXİFLEX, you should avoid prolonged or long exposure to strong sunlight and do not use a solarium or any other UV lamp.
- There is limited experience with the use of MULTIFLEX MOXİFLEX by intravenous administration or ingestion for out-of-hospital pulmonary inflammation (pneumonia).
- The effectiveness of MULTIFLEX MOXİFLEX has not been demonstrated in the treatment of severe burns, deep-tissue infections, osteomyelitis (bone marrow infections) and associated diabetic foot infections.
- If a large blood vessel is diagnosed with enlargement or "swelling" (aortic aneurysm or largevessel peripheral aneurysm)
- If you have had an episode of aortic dissection (rupture of the aortic wall)
- If you have aortic aneurysm or aortic dissection in your family history, or if you have conditions predisposing to other risk factors (eg Marfan syndrome or vascular Ehlers-Danlos syndrome, connective tissue diseases or Takayasu's arteritis, giant cell arteritis)
- Vascular diseases such as Behcet'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 doctor if these warnings apply to you, even at any time in the past.

Use of MULTIFLEX MOXİFLEX with food and drink

MULTIFLEX MOXİFLEX is not affected by food, including dairy products.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant, you should not use MULTIFLEX MOXİFLEX.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

If you are breastfeeding your baby, you should not use MULTIFLEX MOXİFLEX.

Driving and using machines

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

Important information about some of the excipients in MULTIFLEX MOXİFLEX

A MULTIFLEX MOXİFLEX bag (250 mL) contains 34 mmol of sodium. If you have a medical condition such as congestive heart failure, renal failure, nephrotic syndrome (some kind of kidney disease), etc., where sodium intake is of medical importance, the additional sodium load in the infusion solution should be considered. This should also be considered for patients on a controlled sodium diet.

Other medicines and MULTIFLEX MOXİFLEX

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

- If you are using MULTIFLEX MOXİFLEX and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, do not use MULTIFLEX MOXİFLEX 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, sultoprid),
- Tricyclic antidepressants, (e.g. imipramine, amitriptyline, doxepin, clomipramine, nortriptyline, opipramol, amoxapine, tianeptine)
- Some antimicrobials (e.g. sacunavir, sparfloxacin, intravenous erythromycin, pentamidine, antimalarials, especially halofantrin)
- Some antihistamines (e.g. terfenadine, astemizole, mizolastine)
- Other medicines (e.g. cisapiride, intravenous vinamine, bepridil and difemanil)

- 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 MULTIFLEX MOXİFLEX.

- 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 or taking any prescription or over-the-counter medication, please inform your doctor or pharmacist.

3. How to use MULTIFLEX MOXİFLEX

Instructions for proper use and dosage / administration frequency:

Your doctor or health care professional will determine the dose of the drug and administer it to you, depending on your illness.

Method of administration

MULTIFLEX MOXİFLEX is administered as an intravenous infusion (drip injection into a vein) for 60 minutes. Only clear solutions should be used

Different age groups

Use in children: The efficacy and safety of MULTIFLEX MOXİFLEX in children and adolescents under the age of 18 has not been established and should not be used (see section MULTIFLEX DO NOT USE MOXİFLEX in the following cases).

Use in the elderly: No dose adjustment is required for MULTIFLEX MOXİFLEX in the elderly.

Special cases for use

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

Liver failure: No dose adjustment is required in patients with hepatic impairment.

If you have an impression that the effect of MULTIFLEX MOXİFLEX is too strong or too weak, talk to your doctor or pharmacist.

If you use more MULTIFLEX MOXİFLEX than you should

If you think you are using more MULTIFLEX MOXİFLEX than you should, consult your doctor immediately.

Talk to a doctor or pharmacist if you have used more than you should use from MULTIFLEX *MOXİFLEX.*

If you forget to use MULTIFLEX MOXİFLEX

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

If you think you missed the dose of MULTIFLEX MOXİFLEX, consult your doctor immediately.

Possible effects when treatment with MULTIFLEX MOXİFLEX is concluded

Your infection may not have been completely cured after cessation of this medication. If you wish to discontinue treatment with the MULTIFLEX MOXİFLEX infusion solution or MULTIFLEX MOXİFLEX 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Like all medicines, people who are sensitive to the ingredients of MULTIFLEX MOXİFLEX may have side effects.

Very common: can be observed 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.

Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.

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 MULTIFLEX MOXİFLEX and notify your doctor IMMEDIATELY if any of the following occurs, 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 (e.g., 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)

- 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 MULTIFLEX MOXİFLEX use (very rare side effects), immediately tell your doctor following your treatment that you are using MULTIFLEX MOXİFLEX 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 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 MULTIFLEX MOXİFLEX. You may need immediate medical attention or hospitalization.

Other possible side effects of MULTIFLEX MOXİFLEX include the following:

Common

- Nausea
- Diarrhea
- Dizziness
- Stomach-intestine and abdominal pain
- Vomiting
- Headache
- Increases in some liver enzymes (transaminases)
- Infections caused by resistant bacteria or fungi, for example; oral and vaginal infections caused by Candida
- Pain or inflammation at the injection site (inflammation)
- Change in heart graph (ECG) of patients with low potassium levels (hypopotasemia)

Uncommon

- Redness
- Stomach discomfort (indigestion / heartburn)
- Taste disturbance (very rarely loss of this sense)
- Sleep disorders (usually insomnia)
- Increased amount of specific liver enzyme in the blood (gamma-glutamyl-transferase and / or alkaline phosphatase)
- Reduction in white blood cells (leukocytes, neutrophils)
- Constipation
- Itching
- Sensation of dizziness (vertigo or falling)
- Sleepiness
- Flatulence
- 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 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)
- Chills
- Joint pain
- Palpitations
- Irregular and fast heartbeat
- Difficult breathing involving asthma conditions
- An increase in the blood of a special digestive enzyme called amylase
- Uneasiness, anxiety
- Tingling sensation (sards and tingling) and / or numbness
- Hives on the skin
- 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
- Muscle pain
- Allergic reaction
- Bilurubin increase in blood
- Vascular inflammation
- Gastroenteritis
- Sweating (dehydration)
- Severe heart rhythm abnormalities
- Dry skin
- Chest pain (angina pectoris)

Rare

- Muscle contraction
- Muscle cramps
- See, hear or feel things that are not there (hallucinations)
- High blood pressure
- Swelling (on hands, feet, ankles, lips, mouth, throat)

- Low blood pressure
- Renal failure (increase in kidney-specific laboratory test results such as urea and creatinine)
- Liver inflammation
- Mouth inflammation
- Ringing in the ears
- Jaundice (yellowing of eyes or white of skin)
- Skin sensation disorder
- Abnormal dreams
- Concentration disorder
- Difficulty in swallowing
- Change in smell (including loss of sense of smell)
- Impaired balance and poor coordination (due to dizziness)
- Partial or total memory loss
- Hearing impairment including deafness (usually reversible)
- Increase in uric acid in blood
- Emotional instability
- Speech block
- Fainting
- Muscle weakness

Very rare

- Arthritis
- Abnormal heart rhythm
- Increase in skin sensitivity
- Feeling of self-harm (non-self)
- Increase in blood clotting
- Muscle stiffness
- Significant reduction in specific white blood cells (agranulocytosis)

The following symptoms are more common in patients receiving intravenous treatment:

Common

- Increased blood enzyme level (gamma-glutamyl-transferase)

Uncommon

- Severe diarrhea with bloody and / or mucus (antibiotic-related colitis) with very rare life-threatening side effects (complications)

- Abnormally fast heart rhythm
- See, hear or feel things that are not there (hallucinations)
- Low blood pressure
- Renal impairment (increase in kidney specific laboratory test results such as urea and creatinine)
- Kidney failure
- Swelling (hand, foot, ankle, lips, mouth, throat)
- Convulsions

Also, rare side effects following treatment with other quinolones, including MOXİFLEX treatment:

• Decrease in blood sodium levels,
• Increase in blood calcium level,
• A reduction in the number of red blood cells of a particular type (hemolytic anemia),
• Muscle cells damage as well as muscle reactions,
• increased skin sensitivity to sunlight and UV light

If you encounter any side effects not mentioned in this patient information leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store MULTIFLEX MOXİFLEX

Keep MULTIFLEX MOXİFLEX out of the reach of children and in its packaging.

Store at room temperature below 25 ° C.

At cool storage temperatures (below 15 ° C), redissolution precipitation may occur at room temperature. Therefore, it is not recommended to store MULTIFLEX MOXİFLEX in the refrigerator.

Store in original packaging.

Use in accordance with expiration date.

Do not use MULTIFLEX MOXİFLEX after the expiry date on the packaging.

Do not use MULTIFLEX MOXİFLEX if you notice defects in the product / packaging.

Do not dispose of expired or unused medicines! Provide them to the collection system determined by local regulation.

Marketing Authorization Holder:

HAVER FARMA İlaç A.Ş.
Akbaba Mah. Maraş Cad. No:52/2/1
34820 Beykoz / İstanbul

Manufacturing Site:

Osel İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Caddesi No:52
34820 Beykoz / İstanbul

This patient information leaflet approved on 10/09/2020

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

POSOLOGY AND ADMINISTRATION

Adults:

Posology:

For the above indications, MULTIFLEX MOXİFLEX is administered once a day and this dose should not be exceeded.

Administration frequency and duration:

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

Recommended duration of treatment in uncomplicated skin and soft tissue infections: 7 days
Recommended duration of sequential treatment in complicated skin and soft tissue infections (oral administration following intravenous administration): 7-21 days.

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

The recommended treatment duration and dosage for the indication being treated should not be exceeded. MULTIFLEX MOXİFLEX has been studied in clinical trials (complicated skin and soft tissue infections) for up to 21 days of treatment.

Infusion time for intravenous administration is 60 minutes. It should not be administered in less than 60 minutes.

Method of Administration

The MULTIFLEX MOXİFLEX solution can be administered directly or with a T-tube together with infusion solutions to which it is compatible.

The following solutions were found to form stable mixtures at room temperature for 24 hours by co-administration with MULTIFLEX MOXİFLEX and were found to be compatible with MULTIFLEX MOXİFLEX.

- Water for injection
- 0.9% Sodium chloride
- 1 molar Sodium chloride
- 5% Glucose
- 10% Glucose
- 40% Glucose
- 20% Xylitol
- Ringer's Solution
- Ringer's Lactate Solution

If MOXİFLEX is to be co-administered with another drug, the two drugs should be administered separately.

Only clear solutions should be used.

Additional information on special populations

Renal / liver impairment:

Dosage adjustment is not required in patients with renal impairment (including creatinine clearance ≤ 30 mL / min / 1.73m^2) and in chronic dialysis patients such as hemodialysis and continuous ambulatory peritoneal dialysis.

Insufficient data are available in patients with hepatic dysfunction (see section 4.3).

Pediatric population:

The effectiveness and safety of MULTIFLEX MOXİFLEX in children and adolescents under the age of 18 has not been established (see also Section 4.3).

Geriatric population:

No dosage adjustment is required for the elderly.

Other:

No dosage adjustment is required in ethnic groups. MULTIFLEX MOXİFLEX should not be used intraarterially.

OVERDOSE AND TREATMENT

Only limited data on overdose are available. Healthy volunteers received single doses of up to 1200 mg and repeated doses of 600 mg of moxifloxacin for 10 days without any significant

adverse effects. In case of overdose, it is recommended to use appropriate supportive treatment as required by the patient's clinical condition, along with ECG measurements.

INCOMPATIBILITIES

The following infusion solutions have been shown to be incompatible with MULTIFLEX MOXİFLEX. Therefore, MULTIFLEX MOXİFLEX should not be applied with these solutions.

- 10% sodium chloride
- 20% Sodium chloride
- 4.2% sodium hydrogen carbonate
- 8.4% sodium hydrogen carbonate

DISPOSAL OF OTHER MATERIALS AND OTHER SPECIAL PRECAUTIONS

Unused products or waste materials should be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulations". The drug product should not be used if it contains any visible particles or is not clear.