PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

MOXIFLOXACIN 400 mg/250 mL FRESENIUS

Solution for infusion

Moxifloxacin

Sugar free

Read all of this leaflet carefully before you are given MOXIFLOXACIN FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.

What is in this leaflet

1. What MOXIFLOXACIN FRESENIUS is and what it is used for

2. What you need to know before you are given MOXIFLOXACIN FRESENIUS

3. How to use MOXIFLOXACIN FRESENIUS

4. Possible side effects

5. How to store MOXIFLOXACIN FRESENIUS

6. Contents of the pack and other information

1. What MOXIFLOXACIN FRESENIUS is and what it is used for

MOXIFLOXACIN FRESENIUS is used to treat a bacterial infection of the lungs (where the infection was contracted outside a hospital), and severe bacterial infections of the skin, skin tissues and inside your belly (abdomen) where therapy with other appropriate antibiotics have failed, cannot be used, or cannot be tolerated.

2. What you need to know before you are given MOXIFLOXACIN FRESENIUS

You should not receive MOXIFLOXACIN FRESENIUS

- If you are hypersensitive (allergic) to moxifloxacin, any other quinolone antibiotic or any of the other ingredients of MOXIFLOXACIN FRESENIUS (listed in section 6).
- If you have previously experienced side effects with the use of quinolone/fluoroquinolone antibiotics relating to your joints, muscles, ligaments, nerves, central nervous system (brain), epilepsy or mental health (psychiatric disorder).
- If you have severe liver disease, e.g., liver cirrhosis.
- If you are pregnant or breastfeeding your baby (see section “Pregnancy and breastfeeding”).
- If you were born with or have:
    - Any condition with abnormal heart rhythm whether related to QT time prolongation or not (seen on ECG, electrical recording of the heart)
    - A salt imbalance in the blood (especially low levels of potassium or magnesium in the blood)
    - A very slow heart rhythm (called ‘bradycardia’)
    - A weak heart (heart failure)
    - A history of abnormal heart rhythms
- If you are taking other medicines that result in abnormal heart rate or rhythm tracing (ECG) e.g. prolongation of the “QT time”.
- If you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- If you have experienced a previous episode of aortic dissection (a tear in the aortic wall).
- If you have been diagnosed with leaking heart valves (heart valve regurgitation).
- If you have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue

disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner syndrome, Sjogren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Bechet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart].

- If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis).
- **If you or your child are younger than 18 years.**
- If you have moderate to severe impairment of your kidney function and are treated with ACE inhibitors/angiotensin-receptor blockers. Ask your doctor if you are not sure.

Warnings and precautions

Take special care with MOXIFLOXACIN FRESENIUS

- MOXIFLOXACIN FRESENIUS can cause certain changes in the ECG (electronic recording of the heart), especially if you are female or if you are elderly. If you are currently taking other medicines that can reduce your blood potassium levels. If you experience heart palpitations or an irregular heartbeat at any time during treatment, please tell your doctor immediately. If necessary, he/she will then perform an ECG, to determine the pattern of your heartbeat.
- Inform your doctor of any other medicines when taken concurrently with MOXIFLOXACIN FRESENIUS, including over-the-counter/ non-prescription medicines.
- MOXIFLOXACIN FRESENIUS may cause hypersensitivity (allergic) reactions (an anaphylactic reaction/shock), even with the first dose which may be life-threatening or cause life-threatening shock. Discontinue MOXIFLOXACIN FRESENIUS at the first sign of a skin rash or other signs (tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing) indicative of an allergic reaction. In these cases, MOXIFLOXACIN FRESENIUS must be discontinued immediately, and appropriate medical treatment be instituted.

- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.
- MOXIFLOXACIN FRESENIUS may cause a rapid and severe inflammation of the liver which could lead to life- threatening liver failure (including fatal cases). Please tell your doctor before you continue treatment 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.
- **Serious skin reactions:**

  Tell your doctor **before receiving MOXIFLOXACIN FRESENIUS** if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking moxifloxacin.

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

  - SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.

- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities.

- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

- If you develop a serious rash or another of these skin symptoms, you should contact your doctor immediately and treatment with MOXIFLOXACIN FRESENIUS must be stopped.

- Convulsions (fits) have been reported with the use of MOXIFLOXACIN FRESENIUS and you should not receive MOXIFLOXACIN FRESENIUS if you have a history of this condition or continue with treatment if you get fits while receiving MOXIFLOXACIN FRESENIUS.
- If you develop diarrhoea while receiving MOXIFLOXACIN FRESENIUS, your treatment will be stopped. In this situation, you should not receive or use medicines that stop or slow down bowel movement (see section "*You should not receive MOXIFLOXACIN FRESENIUS*").
- MOXIFLOXACIN FRESENIUS can cause tendon (ligament) pain, inflammation (tendinitis) or tendon tearing, during treatment and up to several months after discontinuing MOXIFLOXACIN FRESENIUS treatment. The Achilles tendon (the heel tendon) is most frequently affected. The risk of inflammation and tearing of tendons is increased if you are elderly or if you are currently treated with corticosteroids. At the first sign of any pain or inflammation of the tendon, discontinue treatment; rest and refrain from exercise; and tell your doctor immediately. The recovery process of your tendons, muscles and joints may take weeks or months and full recovery to your pre-treatment status may not occur (see section "*You should not receive MOXIFLOXACIN FRESENIUS*").
- Tell the doctor or laboratory staff that you are receiving MOXIFLOXACIN FRESENIUS if you have to provide a blood or urine sample.
- MOXIFLOXACIN FRESENIUS may interfere with the interpretation of diagnostic culture tests for tuberculosis.

- Your skin may become sensitive to sunlight or UV light when receiving MOXIFLOXACIN FRESENIUS. Avoid prolonged exposure to sunlight and do not use tanning beds or any other UV lamp while receiving MOXIFLOXACIN FRESENIUS. If a sunburn-like reaction or skin eruptions occur, contact your doctor (see section 4, Possible side effects).
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, treatment with MOXIFLOXACIN FRESENIUS should be stopped and you should contact your doctor immediately. The recovery process of your nerve condition may take weeks or months and full recovery to your pre-treatment condition may not occur (see section "*You should not receive MOXIFLOXACIN FRESENIUS*"**).**
- You may experience mental health problems when receiving MOXIFLOXACIN FRESENIUS for the first time.

  Depression or mental health problems can progress to thoughts of suicide or suicide attempts. If this happens, treatment with MOXIFLOXACIN FRESENIUS should be stopped and you should contact your doctor immediately (see section "*You should not receive MOXIFLOXACIN FRESENIUS*").
- If you suffer from myasthenia gravis (type of muscle weakness) you should not receive MOXIFLOXACIN FRESENIUS as it may worsen your disease (see section: "*You should not receive MOXIFLOXACIN FRESENIUS*").
- Consult your doctor before receiving MOXIFLOXACIN FRESENIUS if you are diabetic, because you may experience a risk of change in blood sugar levels with MOXIFLOXACIN FRESENIUS.

  MOXIFLOXACIN FRESENIUS may cause an increase of your blood sugar levels above normal levels (hyperglycaemia) or lowering of your blood sugar levels below normal levels (hypoglycaemia), potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4 Possible side effects). If you suffer from diabetes, your blood sugar should be carefully monitored.

- If you have moderate to severe impairment of your kidney function, or if you are elderly and are treated with ACE inhibitors/angiotensin-receptor blockers to control your blood pressure as this may cause further injury to your kidneys (see section "*You should not receive MOXIFLOXACIN FRESENIUS*"). Your kidney function will be checked before and during treatment if you are receiving fluoroquinolone antibiotics and ACE inhibitors/angiotensin-receptor blockers to control your blood pressure.

Other medicines and MOXIFLOXACIN FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- If you are receiving MOXIFLOXACIN FRESENIUS and other medicines that affect your heart, there is an increased risk for altering your heart rate or rhythm. Therefore, you must tell your doctor, if you are taking any of the medicines that belong to the group of anti-dysrhythmics (medicines to treat your heart rhythm abnormalities), antipsychotics (used for schizophrenia), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides)
- 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, corticosteroids (medicines to treat inflammation or suppress your immune (defence) system), or amphotericin B) or medicines that may cause a slow heart rate because these medicines can also increase the risk of developing serious heart rhythm disturbances while receiving MOXIFLOXACIN FRESENIUS.
- If you take NSAIDs (nonsteroidal anti-inflammatory medicines), used for pain and inflammation. Examples include ibuprofen, indomethacin, diclofenac. You are more likely to have a fit (seizure) if these medicines are taken with MOXIFLOXACIN FRESENIUS.
- If you take digoxin (used to control some heart problems). When used simultaneously, moxifloxacin increased the effect of digoxin. Your doctor may want to monitor you more closely.

- If you are currently taking oral anti-coagulants (e.g., warfarin, a medicine that prevents blood clotting), it may be necessary for your doctor to monitor your blood clotting times.
- Tell your doctor if you are on treatment with ACE inhibitors/angiotensin-receptor blockers used to control your blood pressure as this may cause further injury to your kidneys.
- If you are taking glibenclamide (an antidiabetic medicine), tell your doctor, as moxifloxacin may reduce the effect of glibenclamide and your doctor may want to monitor you more closely.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving MOXIFLOXACIN FRESENIUS.

Pregnancy

If you are pregnant, you should not receive MOXIFLOXACIN FRESENIUS. Safety during pregnancy has not been established. Joint injuries have been reported with quinolone type medicines, which include moxifloxacin (as in MOXIFLOXACIN FRESENIUS).

In animal studies toxic effects on reproduction have been reported.

Breastfeeding

If you are receiving MOXIFLOXACIN FRESENIUS, you should not breastfeed your baby, as moxifloxacin is excreted in human breastmilk. Moxifloxacin, as in MOXIFLOXACIN FRESENIUS has been shown to cause lesions in the cartilage (connective tissue) between weight-bearing joints of young animals.

Fertility

No information available.

Driving and using machines

MOXIFLOXACIN FRESENIUS may affect your ability to drive and operate machinery. MOXIFLOXACIN FRESENIUS may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision or you may faint for a short period.

MOXIFLOXACIN FRESENIUS contains sodium

MOXIFLOXACIN FRESENIUS contains 747,5 mg (32,5 mmol) sodium (as acetate and as sulphate). If you are on a controlled-salt diet, please inform your doctor immediately.

3. How to use MOXIFLOXACIN FRESENIUS

MOXIFLOXACIN FRESENIUS is a solution for infusion.

Your doctor will prescribe the correct dose for your condition.

The duration of your treatment will be determined by your doctor. MOXIFLOXACIN FRESENIUS will be administered into one of your veins.

MOXIFLOXACIN FRESENIUS will always be given to you by a doctor or a healthcare professional.

If you receive more MOXIFLOXACIN FRESENIUS than you should

Since a healthcare provider will administer MOXIFLOXACIN FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of MOXIFLOXACIN FRESENIUS

Since a healthcare provider will administer MOXIFLOXACIN FRESENIUS, it is unlikely that the dose will be missed.

If you stop using MOXIFLOXACIN FRESENIUS

You should always consult your doctor before deciding to interrupt the course of treatment or stop receiving MOXIFLOXACIN FRESENIUS altogether.

4. Possible side effects

MOXIFLOXACIN FRESENIUS can have side effects.

Not all side effects reported for MOXIFLOXACIN FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving MOXIFLOXACIN FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving MOXIFLOXACIN FRESENIUS and tell your doctor immediately:

- angioedema (rapid swelling of the skin and mucous membranes of the face, lips, tongue, or throat with difficulty to breathe)
- anaphylactic reaction/shock which is a severe sudden allergic reaction and is rapid in onset. Symptoms of anaphylactic reaction include: dizziness, feeling dizzy, sick or faint or experiencing dizziness when standing up), tightness in the chest, loss of consciousness, difficulty in breathing, swelling of the face, lips, tongue, throat and airways (breathing tubes), blueness of the skin, low blood pressure, heart failure, and can result in death;
- sudden severe pain in your chest, abdomen (tummy) or back;
- severe dizziness, fainting, fast or pounding heartbeats;
- sudden pain, snapping or popping sound, bruising, swelling, tenderness, stiffness, or loss of movement in any of your muscles, ligaments or joints;
- Cases of enlargement or weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2;
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma);
- diarrhoea that is watery or bloody;
- confusion, hallucinations, depression, unusual thoughts or behaviour;
- seizure (convulsions);

- pale or yellowed skin, dark coloured urine, fever, weakness;
- urinating less than usual or not at all;
- easy bruising or bleeding;
- numbness, tingling, or unusual pain anywhere in your body;
- the first sign of any skin rash, no matter how mild; or serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (potentially life threatening);
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH).

<u>Frequent side effects include</u>

- Infections caused by fungi (oral and vaginal infections/thrush caused by Candida)
- Anaemia (low red blood cell count), leukopenia (low white blood cell count), neutropenia (low numbers of special white blood cells – neutrophils), thrombocytopenia (decrease or increase of special cells necessary for blood clotting), prolonged prothrombin time or increased INR (decreased blood clotting)
- Allergic reactions, pruritus (itching), rash, urticaria (skin hives), blood eosinophilia (increased specialised white blood cells – eosinophils)
- Increased blood lipids/fats
- Anxiety reactions, restlessness/agitation
- Headache, dizziness, par- and dysesthesia (tingling sensation (pins and needles) and/or numbness), taste disorders or loss of taste, confusion and disorientation, sleep disorders, tremor (shaking), vertigo (sensation of dizziness, spinning or falling over), somnolence (sleepiness)
- Visual disturbances including double and blurred vision

- QT prolongation in patients with hypokalaemia (delayed electrical recovery time within the heart as shown by ECG in patients with low blood potassium level), QT prolongation (delayed electrical recovery time within the heart shown by ECG), palpitations (irregular heartbeat), tachycardia (fast heartbeat), vasodilatation (widening of blood vessels)
- Dyspnoea (difficulty in breathing including asthma)
- Nausea, vomiting, gastrointestinal and abdominal pain, diarrhoea, decreased appetite and food intake, constipation, dyspepsia (upset stomach, indigestion and/or heartburn), flatulence (wind), gastroenteritis (inflammation of the stomach), increased amylase (a special digestive enzyme in the blood)
- Increase in transaminases (a special liver enzyme in the blood), impaired liver function, including 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 diarrhoea or reduced fluid intake)
- Feeling unwell (predominantly weakness or tiredness), unspecific aches and pains such as back, chest, pelvic and extremities pains, sweating

<u>Less frequent side effects include</u>

- Abnormal thromboplastin level (special enzyme in the blood involved in blood coagulation), changes in prothrombin level and INR (increased or abnormal blood clotting)
- A drop in the number of red and white blood cells and platelets (pancytopenia)
- Anaphylactic reaction (severe, sudden allergic reaction for example difficulty in breathing, drop of blood pressure, fast pulse), angioedema (swelling of the face, lips, tongue, throat and airway), anaphylactic shock (which may be life-threatening)
- Blood-glucose disorders (high blood sugar – hyperglycaemia or low blood sugar - hypoglycaemia), hyperuricemia (increased blood uric acid)

- Depression, hallucinations, feelings of not being yourself, psychotic reactions (potentially leading to self-harm, such as thought to kill oneself, or suicide attempts)
- Reduced skin sensation, smell disorders, abnormal dreams, disturbed coordination due to dizziness or vertigo (may lead to fall with injuries), seizures (fits), disturbed attention, impaired speech, amnesia (partial or total loss of memory), peripheral neuropathy and polyneuropathy (troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities), increased sensitivity of the skin
- Temporary loss of vision
- Ringing in the ears (tinnitus), hearing impairment including deafness (usually reversible)
- Abnormal fast heart rhythm, syncope (fainting), high blood pressure, low blood pressure, unspecified abnormal heart rhythms, Torsade de Pointes (life-threatening irregular heartbeat), cardiac arrest (stopping of heartbeat)
- Dysphagia (difficulty in swallowing), stomatitis (inflammation of the mouth), antibiotic-associated colitis (severe diarrhoea containing blood and/or mucous, which may be life-threatening)
- Jaundice (yellowing of the whites of the eyes or skin), hepatitis (inflammation of the liver), severe inflammation of the liver (potentially leading to life-threatening liver failure)
- Tendinitis (pain and swelling of the tendons), increased muscle tone and cramping, muscular weakness, tendon rupture, arthritis (inflammation of joints), gait disturbance (caused by muscular, tendon or joint symptoms), worsening of the symptoms of myasthenia gravis
- Impairment or failure of the kidneys (due to dehydration)
- Oedema (swelling of the hands, feet, ankles, lips, mouth, throat)

<u>Not known (frequency cannot be estimated from the available data)</u>

- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis)

- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (drug reaction with eosinophilia and systemic symptoms which is also known as DRESS or drug hypersensitivity syndrome)
- Increased sensitivity of the skin to sunlight or UV light (see also section 2, Warnings and precautions)
- Sharply demarcated, erythematous patches with/without blistering that develop within hours of administration of moxifloxacin and heals with post inflammatory residual hyperpigmentation; it usually recurs at the same site of the skin or mucous membrane upon subsequent exposure to moxifloxacin
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis)

<u>The following side effects have been observed more frequently in patients treated with intravenously followed by oral treatment:</u>

- Increased gamma-glutamyl-transferase (liver enzyme in the blood), abnormal fast heart rhythm, low blood pressure, oedema (swelling of the hands, feet, ankles, lips, mouth or throat), antibiotic- associated colitis (severe diarrhoea containing blood and /or mucous), seizures (fits), hallucinations, impairment and failure of kidneys.

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med

Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store MOXIFLOXACIN FRESENIUS

Store all medicines out of reach of children.

Store at or below 30 °C in the original packaging and protect from light (keep bags in their overwraps until required for use). Do not store below 15 °C. At temperatures below 15 ºC precipitation may occur, which will re-dissolve at room temperature (15℃ to 25℃). It is therefore recommended not to store the infusion solution in a refrigerator. Protect from light. Keep the flexibags in the overwrap/pouch or the bottles in the outer cartons until required for use.

MOXIFLOXACIN FRESENIUS should be inspected visually for particles prior to administration. Only clear solution free from particles should be used.

6. Contents of the pack and other information

What MOXIFLOXACIN FRESENIUS contains

The active substance is moxifloxacin. Each bag/bottle contains 400 mg of moxifloxacin (as hydrochloride).

The other ingredients are: Sodium acetate trihydrate, disodium sulphate, water for injection, sulphuric acid (for pH-adjustment). (See section "MOXIFLOXACIN FRESENIUS contains sodium").

What MOXIFLOXACIN FRESENIUS looks like and contents of the pack

MOXIFLOXACIN FRESENIUS is a clear, yellow solution.

Two packing systems are provided:

- 300 mL Polyolefin *(***Free***flex*®) bags with polypropylene port, sealed in aluminium foil overwrap.

- The ***KabiPac***® packaging system consists of a primary container of 250 mL low density polyethylene blow-fill-seal bottle. The container's head is protected by a secondary packaging closure, consisting of HDPE/LDPE.

Pack sizes: 1, 10, 20, 25 and 40.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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Registration number

49/20.1.1/0675

Access to the corresponding Professional Information

The professional information will be printed and packed with the product.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

MOXIFLOXACIN 400 mg/250 mL FRESENIUS

Oplossing vir infusie

Moksifloksasien

Suikervry

Lees die hele inligtingsblad aandagtig deur voordat MOXIFLOXACIN FRESENIUS aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

1. Wat is MOXIFLOXACIN FRESENIUS en waarvoor word dit gebruik

2. Wat jy moet weet voordat MOXIFLOXACIN FRESENIUS aan jou gegee word

3. Hoe om MOXIFLOXACIN FRESENIUS te gebruik

4. Moontlike newe-effekte

5. Hoe om MOXIFLOXACIN FRESENIUS te bewaar

6. Inhoud van die pakkie en ander inligting

1. Wat is MOXIFLOXACIN FRESENIUS en waarvoor word dit gebruik

MOXIFLOXACIN FRESENIUS word gebruik om bakteriële infeksies in die longe te behandel (indien die infeksie buite 'n hospitaal opgedoen is) en erge bakteriële infeksies van die vel,

velweefsel en binne die buik (abdomen) wat nie met ander toepaslike antibiotika behandel kon word nie, of nie gebruik kan word nie, of verdra word nie.

2. Wat jy moet weet voordat jy MOXIFLOXACIN FRESENIUS ontvang

Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie

- Indien jy hipersensitief (allergies) is vir moksifloksasien, enige ander kinoloon-antibiotikum of enige van die ander bestanddele van MOXIFLOXACIN FRESENIUS (gelys in afdeling 6).
- Indien jy voorheen newe-effekte gehad het met die gebruik van kinoloon/fluoorkinoloon antibiotika wat verband gehou het met jou gewrigte, spiere, ligamente, senuwees, sentrale senuweestelsel (brein), epilepsie of geestesgesondheid (psigiatriese versteurings).
- Indien jy erge lewersiekte, bv. lewersirrose het.
- Indien jy swanger is of jou baba borsvoed (sien "Swangerskap, borsvoeding en vrugbaarheid").
- Indien jy gebore is met die volgende, of dit tans het:
    - Enige siektetoestand met 'n abnormale hartritme, hetsy dit verwant is aan QT-tydverlenging of nie (gesien op die EKG, die elektriese opnames van die hart)
    - 'n Wanbalans van soute in die bloed (buitengewoon lae bloedvlakke van kalium of magnesium)
    - 'n Baie stadige hartritme (genaamd 'bradikardie')
    - 'n Swak hart (hartversaking)
    - 'n Geskiedenis van abnormale hartritme
- Indien jy ander medisyne gebruik wat lei tot 'n abnormale hartklop en/of ritmegrafiek (EKG), bv. verlengde "QT-interval".
- Indien jy met 'n vergroting of 'uitbulting' van 'n groot bloedvat (aorta-aneurisme of groot perifere bloedvat-aneurisme) gediagnoseer is.
- Indien jy reeds 'n aorta-disseksie ('n skeur in die aortawand) gehad het.
- Indien jy met lekkende hartkleppe (hartklep ontoereikendheid) gediagnoseer is.

- Indien jy 'n familiegeskiedenis van aorta-aneurismes, aortadisseksie of aangebore hartklepgebrek, of ander risikofaktore of predisponerende siektetoestande het (bv. bindweefselsiektes soos Marfan-sindroom of Ehlers-Danlos-sindroom, Turner-sindroom, Sjögren-sindroom ['n inflammatoriese outo-immuunsiekte], of vaskulêre siektes soos Takayasu-arteritis, reuse-sel arteritis, Bechet se siekte, hoë bloeddruk of bekende arteriosklerose, rumatoïede artritis ['n siekte van die gewrigte] of endokarditis ['n infeksie van die hart]).
- Indien jy miastenie gravis het (abnormale spiermoegheid wat tot swakheid en in ernstige gevalle verlamming lei).
- **Indien jy of jou kind jonger as 18 jaar is.**
- Indien jy matig-tot-ernstige belemmerde nierfunksie het en behandel word met AOE-inhibitore/angiotensienreseptorblokkers. Vra jou dokter as jy nie seker is nie.

Waarskuwings en voorsorgmaatreëls

<u>Wees veral versigtig vir MOXIFLOXACIN FRESENIUS</u>

- MOXIFLOXACIN FRESENIUS kan sekere veranderinge in die EKG (elektroniese opname van die hart) veroorsaak, veral as jy vroulik is of as jy bejaard is. Indien jy tans ander medisyne neem wat jou bloedkaliumvlakke kan verminder. Indien jy op enige tydstip tydens die behandeling hartkloppings of 'n onreëlmatige hartklop ervaar, lig jou dokter asseblief dadelik in. Indien nodig, sal hy/sy 'n EKG doen om die patroon van jou hartklop te bepaal.
- Lig jou dokter in van enige ander medisyne wanneer dit saam met MOXIFLOXACIN FRESENIUS geneem word, insluitend oor-die-toonbank/nie-voorskrif medisyne.
- MOXIFLOXACIN FRESENIUS kan hipersensitiwiteit (allergiese) reaksies ('n anafilaktiese reaksie/skok) veroorsaak, selfs met die eerste dosis, wat lewensgevaarlik kan wees of lewensgevaarlike skok kan veroorsaak. Staak MOXIFLOXACIN FRESENIUS by die eerste teken van 'n veluitslag of ander tekens (benoude bors, duiseligheid, naarheid of floute, of as jy duiselig voel wanneer jy opstaan) wat dui op 'n allergiese reaksie. In hierdie gevalle

moet MOXIFLOXACIN FRESENIUS dadelik gestaak word en toepaslike mediese behandeling ingestel word.

- Indien jy skielike, erge pyn in jou buik, bors of rug voel, wat simptome van 'n aorta-aneurisme of disseksie kan wees, gaan onmiddellik na die noodafdeling. Jou risiko kan verhoog word as jy met sistemiese kortikosteroïede behandel word.
- Indien jy skielik kortasemigheid ervaar, veral wanneer jy plat in die bed lê, of as jou enkels, voete of maag swel, of as jy nuwe hartkloppings begin kry (gevoel van 'n vinnige of onreëlmatige hartklop), moet jy dadelik 'n dokter kontak.
- MOXIFLOXACIN FRESENIUS kan 'n vinnige en ernstige ontsteking van die lewer veroorsaak wat tot lewensgevaarlike lewerversaking kan lei (insluitend sterfgevalle). Lig asseblief jou dokter in voordat jy voortgaan met die behandeling as jy tekens ontwikkel soos om skielik ongesteld en/of naar te voel en as dit gepaardgaan met geel verkleuring van die oogwitte, donker urien, jeukerige vel, 'n neiging om te bloei.
- **Ernstige velreaksies:**

  Lig jou dokter in **voordat jy MOXIFLOXACIN FRESENIUS ontvang**, indien jy al ooit 'n erge veluitslag of velafskilfering, blase en/of mondsere ontwikkel het nadat jy moksifloksasien geneem het.

  Met die gebruik van MOXIFLOXACIN FRESENIUS is ernstige velreaksies, insluitend Stevens-Johnson-sindroom, toksiese epidermale nekrolise, en akute veralgemeende eksanteemagtige pustulose (AGEP) en geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS) met die gebruik van moksifloksasien, soos in MOXIFLOXACIN FRESENIUS, aangemeld.

  - SJS/TEN kan aanvanklik verskyn as rooierige, teiken-agtige vlekke of ronde kolle, dikwels met blase in die middel van die romp. Daarbenewens kan sere in die mond, keel, neus, geslagsorgane en oë (rooi en geswelde oë) voorkom. Hierdie ernstige veluitslag word dikwels voorafgegaan deur koors en/of griepagtige simptome. Die uitslag kan vorder tot uitgebreide afskilfering van die vel en lewensbedreigende komplikasies, of dit kan noodlottig wees.

- AGEP verskyn by die aanvang van behandeling as 'n rooi, skubberige wydverspreide uitslag met knoppe onder die vel en blase, gepaardgaande met koors. Die mees algemene ligging: hoofsaaklik gelokaliseer op die velvoue, romp en boonste ledemate.

- DRESS presenteer aanvanklik met griepagtige simptome en 'n uitslag op die gesig, dan 'n wydverspreide uitslag met hoë liggaamstemperatuur, verhoogde lewerensieme in bloedtoetse en 'n toename in 'n sekere tipe witbloedsel (eosinofilie) en vergrote limfknope.

- Indien jy 'n ernstige uitslag of een van hierdie velsimptome ontwikkel, moet jy dadelik jou dokter kontak en die behandeling met MOXIFLOXACIN FRESENIUS moet gestaak word.

- Stuiptrekkings (toevalle) is met die gebruik van MOXIFLOXACIN FRESENIUS aangemeld en jy moet nie MOXIFLOXACIN FRESENIUS ontvang as jy 'n geskiedenis hiervan het nie en jy moet nie voortgaan met behandeling as jy toevalle kry terwyl jy MOXIFLOXACIN FRESENIUS ontvang nie.
- Indien jy diarree ontwikkel terwyl jy MOXIFLOXACIN FRESENIUS ontvang, sal jou behandeling gestaak word. In hierdie situasie moet jy nie medisyne ontvang of gebruik wat jou stoelgang stop of vertraag nie (sien afdeling “Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie”).
- MOXIFLOXACIN FRESENIUS kan tendon (ligament) pyn, inflammasie (tendinitis) of skeuring van 'n tendon veroorsaak, tydens behandeling en tot etlike maande nadat MOXIFLOXACIN FRESENIUS behandeling gestaak is. Die Achilles-tendon (die haksening) word die algemeenste aangetas. Die risiko van inflammasie en skeuring van die tendons word verhoog as jy bejaard is of as jy tans met kortikosteroïede behandel word. By die eerste teken van enige pyn of ontsteking van die tendon, staak behandeling; rus en weerhou jou van oefening; en lig jou dokter dadelik in. Dit kan weke of maande neem vir jou tendons, spiere en gewrigte om te genees, en hulle sal dalk nie ten volle herstel tot die toestand waarin hulle voor die behandeling was nie (sien afdeling "Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie").
- Lig die dokter of laboratoriumpersoneel in dat jy MOXIFLOXACIN FRESENIUS ontvang as jy 'n bloed- of urienmonster moet verskaf.

- MOXIFLOXACIN FRESENIUS kan die interpretasie van diagnostiese kultuurtoetse vir tuberkulose beïnvloed.
- Jou vel kan meer gevoelig raak vir sonlig of UV-lig as jy MOXIFLOXACIN FRESENIUS ontvang. Vermy langdurige blootstelling aan sonlig en moenie sonbeddens gebruik of enige ander UV-lamp terwyl jy MOXIFLOXACIN FRESENIUS ontvang nie. Indien 'n sonbrand-agtige reaksie of veluitslag voorkom, kontak jou dokter (sien afdeling 4, Moontlike newe-effekte).
- Jy kan simptome van neuropatie soos pyn, branderigheid, prikkelgevoel, gevoelloosheid en/of swakheid in jou ledemate ervaar. Indien dit gebeur, moet behandeling met MOXIFLOXACIN FRESENIUS gestaak word en jy moet dadelik jou dokter kontak. Die herstelproses van jou senuweesiekte kan weke of maande duur en jy sal dalk nie heeltemal herstel tot jou voorbehandelingstoestand nie (sien afdeling “Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie”).
- Jy kan geestesgesondheidsprobleme ervaar wanneer jy MOXIFLOXACIN FRESENIUS vir die eerste keer ontvang.

  Depressie of geestesgesondheidsprobleme kan vorder tot gedagtes oor selfdood of selfdoodpogings. Indien dit gebeur, moet behandeling met MOXIFLOXACIN FRESENIUS gestaak word en jy moet dadelik jou dokter kontak (sien afdeling "Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie").
- Indien jy ly aan miastenie gravis ('n tipe spierswakheid) moet jy nie MOXIFLOXACIN FRESENIUS ontvang nie want dit kan jou siekte vererger (sien afdeling: "Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie").
- Indien jy 'n diabeet is, raadpleeg jou dokter voordat jy MOXIFLOXACIN FRESENIUS ontvang, want jy kan die risiko loop van 'n verandering in jou bloedsuikervlakke met MOXIFLOXACIN FRESENIUS.

  MOXIFLOXACIN FRESENIUS kan 'n toename in jou bloedsuikervlakke veroorsaak tot bo die normale vlakke (hiperglukemie), of verlaging van jou bloedsuikervlakke tot onder die normale vlakke (hipoglukemie), wat moontlik kan lei tot verlies van bewussyn

(hipoglukemiese koma) in erge gevalle (sien afdeling 4 Moontlike newe-effekte). Indien jy ly aan diabetes moet jou bloedsuiker noukeurig dopgehou word.

- Indien jy matig-tot-ernstige verswakte nierfunksie het, of as jy bejaard is en behandel word met AOE-inhibitore/angiotensien-reseptorblokkers om jou bloeddruk te beheer, aangesien dit verdere skade aan jou niere kan veroorsaak (sien afdeling “Jy moet nie MOXIFLOXACIN FRESENIUS ontvang nie"). Jou nierfunksie sal voor en tydens die behandeling gekontrolleer word indien jy fluoorkinoloon antibiotika ontvang en AOE-inhibitore/ angiotensien-reseptorblokkers om jou bloeddruk te beheer.

Ander medisyne en MOXIFLOXACIN FRESENIUS

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Indien jy MOXIFLOXACIN FRESENIUS ontvang en ander medisyne wat jou hart kan aantas, is daar 'n verhoogde risiko dat die kloptempo van jou hart of hartritme kan verander. Jy moet dus jou dokter inlig as jy enige medisyne neem wat tot die groep anti-disritmiese middels behoort (medisyne om jou hartritme-afwykings te behandel), antipsigotika (gebruik vir skisofrenie), trisikliese antidepressante, sommige antimikrobiese middels (wat behoort tot die groep makroliede).
- Jy moet jou dokter inlig indien jy ander medisyne gebruik wat jou bloedkaliumvlakke kan verlaag (bv. sommige diuretika, sommige lakseermiddels en enemas, kortikosteroïede (medisyne om inflammasie te behandel of jou immuunstelsel (verdediging) te onderdruk), of amfoterisien B) of medisyne wat 'n stadige hartklop kan veroorsaak omdat hierdie medisyne ook die risiko om ernstige hartritmestoornisse te ontwikkel terwyl MOXIFLOXACIN FRESENIUS ontvang word, kan verhoog.
- Indien jy NSAIG’s (niesteroïdale anti-inflammatoriese geneesmiddels), gebruik vir pyn en ontsteking, neem. Voorbeelde sluit in ibuprofeen, indometasien, diklofenak. Indien jy hierdie medisyne saam met MOXIFLOXACINE FRESENIUS neem, is die kans groter dat jy 'n 'n toeval (aanval) kry.

- Indien jy digoksien neem (gebruik om sekere hartprobleme te beheer). Wanneer dit gelyktydig gebruik word, verhoog moksifloksasien die effek van digoksien. Jou dokter sal jou dalk meer deeglik wil moniteer.
- Indien jy tans mondelike antistolmiddels neem (soos warfarien, 'n medisyne wat voorkom dat bloed stol), sal jou dokter dalk jou bloedstollingstye moet monitor.
- Lig jou dokter in as jy behandel word met AOE-inhibitore/angiotensien-reseptorblokkers om jou bloeddruk te beheer, aangesien dit bykomende skade aan jou niere kan veroorsaak.
- Indien jy glibenklamied neem ('n antidiabetiese medisyne), lig jou dokter in, want moksifloksasien kan die effek van glibenklamied verminder en jou dokter sal jou moontlik meer noulettend wil moniteer.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy MOXIFLOXACIN FRESENIUS ontvang.

Swangerskap

Indien jy swanger is moet jy nie MOXIFLOXACIN FRESENIUS ontvang nie. Veiligheid tydens swangerskap is nie vasgestel nie. Beserings aan gewrigte is met kinoloon-tipe medisyne, wat moksifloksasien (soos in MOXIFLOXACIN FRESENIUS) insluit, aangemeld.

In studies met diere is toksiese effekte op voortplanting aangemeld.

Borsvoeding

Indien jy MOXIFLOXACIN FRESENIUS ontvang, moet jy nie jou baba borsvoed nie, want moksifloksasien word in menslike borsmelk uitgeskei. Daar was aangetoon dat moksifloksasien, soos in MOXIFLOXACIN FRESENIUS, letsels in die kraakbeen (bindweefsel) tussen die gewigdraende gewrigte van jong diere veroorsaak.

Vrugbaarheid

Geen inligting beskikbaar nie.

Bestuur en die gebruik van masjinerie

MOXIFLOXACIN FRESENIUS kan jou vermoë om te bestuur en masjinerie te hanteer aantas. MOXIFLOXACIN FRESENIUS kan jou duiselig of lighoofdig maak, jy kan 'n skielike, tydelike verlies van visie ervaar, of vir 'n klein rukkie flou word.

MOXIFLOXACIN FRESENIUS bevat natrium

MOXIFLOXACIN FRESENIUS bevat 747,5 mg (32,5 mmol) natrium (as asetaat en as sulfaat). Indien jy op 'n beperkte sout dieet is, lig asseblief dadelik jou dokter in.

3. Hoe om MOXIFLOXACIN FRESENIUS te gebruik

MOXIFLOXACIN FRESENIUS is 'n oplossing vir infusie.

Jou dokter sal die regte dosis vir jou siektetoestand voorskryf.

Die duur van jou behandeling sal deur jou dokter bepaal word. MOXIFLOXACIN FRESENIUS sal in een van jou are toegedien word.

MOXIFLOXACIN FRESENIUS sal altyd deur 'n dokter of gesondheidsorgkundige aan jou toegedien word.

Indien jy meer MOXIFLOXACIN FRESENIUS ontvang het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer MOXIFLOXACIN FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering hanteer.

Indien jy 'n dosis van MOXIFLOXACIN FRESENIUS oorslaan

Aangesien 'n gesondheidsorgverskaffer MOXIFLOXACIN FRESENIUS sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

Indien jy ophou om MOXIFLOXACIN FRESENIUS te gebruik

Jy moet altyd jou dokter raadpleeg voordat jy besluit om die behandelingskursus te onderbreek of heeltemal op te hou om MOXIFLOXACIN FRESENIUS te ontvang.

4. Moontlike newe-effekte

MOXIFLOXACIN FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir MOXIFLOXACIN FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy MOXIFLOXACIN FRESENIUS ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om MOXIFLOXACIN FRESENIUS te ontvang en lig jou dokter dadelik in:

- angio-edeem (vinnige swelling van die vel en slymvliese van die gesig, lippe, tong of keel, met probleme om asem te haal);
- anafilaktiese reaksie/skok, dit is 'n skielike, erge allergiese reaksie wat vinnig begin. Simptome van 'n anafilaktiese reaksie sluit in: duiseligheid (voel duiselig, naar of flou, of duiseligheid as jy opstaan), benoudheid in die bors, verlies van bewussyn, moeilike asemhaling, swelling van die gesig, lippe, tong, keel en lugweë (asemhalingskanale), blou vel, lae bloeddruk, hartversaking, en dit kan noodlottig wees;
- skielike erge pyn in jou bors, buik (maag) of rug;
- erge duiseligheid, floute, vinnige of stampende hartklop;
- skielike pyn, breek- of plofgeluid, kneusing, swelling, gevoeligheid, styfheid of verlies van beweging in enige van jou spiere, ligamente of gewrigte;
- Gevalle van verwyding of verswakking van die aortawand of skeuring van die aortawand (aneurismes en disseksies) wat kan bars en noodlottig kan wees, en lekkende hartkleppe is by pasiënte wat fluoorkinolone ontvang aangemeld. Sien ook afdeling 2;
- verlies van bewussyn weens erge afname in bloedsuikervlakke (hipoglukemiese koma);
- diarree wat waterig of bloederig is;
- verwardheid, hallusinasies, depressie, ongewone gedagtes of gedrag;
- stuipe (stuiptrekkings);

- bleek of vergeelde vel, donker gekleurde urien, koors, swakheid;
- urineer minder as gewoonlik of glad nie;
- kneus of bloei maklik;
- gevoelloosheid, prikkelgevoel, of ongewone pyn op enige deel van jou liggaam;
- die eerste teken van enige veluitslag, ongeag hoe lig; of erge veluitslag insluitend Stevens-Johnson-sindroom en toksiese epidermale nekrolise. Dit kan voorkom as rooierige, teiken-agtige kolle of sirkelvormige kolle, dikwels met blase in die middel, op die romp, afskilfering van die vel, sere in die mond, keel, neus, geslagsdele en oë en kan gepaard gaan met koors en griepagtige simptome (moontlik lewensgevaarlik);
- Sindroom wat geassosieer word met verswakte wateruitskeiding en lae natriumvlakke (SIADH).

<u>Gereelde newe-effekte sluit in</u>

- Infeksies veroorsaak deur swamme (mondelike en vaginale infeksies/sproei veroorsaak deur Candida)
- Anemie (lae rooibloedseltelling), leukopenie (lae witbloedseltelling), neutropenie (lae aantal spesiale witbloedselle - neutrofiele), trombositopenie (afname of toename van spesiale selle nodig vir bloedstolling), verlengde protrombientyd of verhoogde INR (verminderde bloedstolling)
- Allergiese reaksies, pruritus (jeuk), uitslag, urtikarie (netelroos op die vel), bloed-eosinofilie (verhoogde gespesialiseerde witbloedselle - eosinofiele)
- Verhoogde lipiede/vette in bloed
- Angsreaksies, rusteloosheid/onrustigheid
- Hoofpyn, duiseligheid, par- en disestesie (prikkelende sensasie (speld-en-naaldprikkels) en/of gevoelloosheid), smaakversteuring of smaakverlies, verwarring en disoriëntasie, slaapversteuring, tremor (bewerigheid), vertigo (gevoel van duiseligheid, spin of omval), lomerigheid (slaperigheid)

- Gesigsversteurings insluitend dubbele en dowwe visie
- QT-verlenging by pasiënte met hipokalemie (vertraagde elektriese hersteltyd binne die hart, soos getoon deur die EKG by pasiënte met 'n lae bloedkaliumvlak), QT-verlenging (vertraagde elektriese hersteltyd binne die hart, aangetoon deur die EKG), hartkloppings (onreëlmatige hartklop), tagikardie (vinnige hartklop), vasodilatasie (verwyding van die bloedvate)
- Dispnee (moeilike asemhaling, insluitend asma)
- Naarheid, braking, maagdermkanaal- en buikpyn, diarree, verminderde eetlus en voedselinname, hardlywigheid, dispepsie (omgekrapte maag, swak spysvertering en/of sooibrand), flatulensie (winderigheid), gastroënteritis (inflammasie van die maag), verhoogde amilase ('n spesiale spysverteringsensiem in die bloed)
- Toename in transaminases ('n spesiale lewerensiem in die bloed), swak lewerfunksie, insluitend LDH-verhoging ('n spesiale lewerensiem in die bloed), toename van bilirubien in die bloed, toename van gammaglutamieltransferase en/of alkaliese fosfatase in die bloed (spesiale lewerensieme in die bloed)
- Artralgie (spierpyn), mialgie (spierpyn)
- Dehidrasie (veroorsaak deur diarree of verminderde vloeistofinname)
- Ongesteld voel (hoofsaaklik swakheid of moegheid), onspesifieke pyne en skete soos rug-, bors-, bekken- en ledemaatpyne, sweet

<u>Minder gereelde newe-effekte sluit in</u>

- Abnormale tromboplastienvlak (spesiale ensiem in die bloed betrokke by bloedstolling), veranderinge in die protrombienvlak en INR (verhoogde of abnormale bloedstolling)
- 'n Daling in die aantal rooi- en witbloedselle en plaatjies (pansitopenie)
- Anafilaktiese reaksie (erge, skielike allergiese reaksie, byvoorbeeld probleme met asemhaling, daling van bloeddruk, vinnige polsslag), angio-edeem (swelling van die gesig, lippe, tong, keel en lugweg), anafilaktiese skok (wat lewensgevaarlik kan wees)

- Bloedglukose afwykings (hoë bloedsuiker - hiperglukemie of lae bloedsuiker - hipoglukemie), hiperurisemie (verhoogde bloeduriensuur)
- Depressie, hallusinasies, voel of jy nie jouself is nie, psigotiese reaksies (kan moontlik lei tot selfskade, soos gedagtes om jou eie lewe te neem, of selfdoodpogings)
- Vel voel minder gevoelig, reukversteurings, abnormale drome, versteurde koördinasie weens duiseligheid of vertigo (kan lei tot val met beserings), aanvalle (toevalle), versteurde aandag, verswakte spraak, amnesie (gedeeltelike of totale verlies van geheue), perifere neuropatie en poli-neuropatie (probleme wat met die senuweestelsel geassosieer word soos pyn, brandgevoel, tinteling, gevoelloosheid en/of swakheid van die ledemate), vel word meer gevoelig
- Tydelike sigverlies
- Gesuis in die ore (tinnitus), verswakte gehoor insluitend doofheid (gewoonlik omkeerbaar)
- Abnormale vinnige hartritme, sinkopee (floute), hoë bloeddruk, lae bloeddruk, ongespesifiseerde abnormale hartritme, Torsades de Pointes (lewensgevaarlike onreëlmatige hartklop), hartstilstand (stop van hartklop)
- Disfagie (sukkel om te sluk), stomatitis (ontsteking van die mond), antibiotika-geassosieerde kolitis (erge diarree wat bloed en/of slym bevat, wat lewensgevaarlik kan wees)
- Geelsug (geel verkleuring van die oogwitte of vel), hepatitis (ontsteking van die lewer), erge inflammasie van die lewer (wat moontlik tot lewensgevaarlike lewerversaking kan lei)
- Tendinitis (pyn en swelling van die tendons), verhoogde spiertonus en krampe, spierswakheid, tendon-skeuring, artritis (ontsteking van gewrigte), manier van loop aangetas (veroorsaak deur spier-, tendon- of gewrigsimptome), verergering van die simptome van miastenie gravis
- Verswakking of versaking van die niere (weens ontwatering)
- Edeem (swelling van die hande, voete, enkels, lippe, mond, keel)

Onbekend (frekwensie kan nie uit die beskikbare data geskat word nie)

- 'n Rooi, skubberige wydverspreide uitslag met knoppe onder die vel en blase, gepaardgaande met koors by aanvang van behandeling (akute veralgemeende eksanteemagtige pustulose)
- Wydverspreide veluitslag, hoë liggaamstemperatuur, verhoogde lewerensieme, veranderinge in bloedtelling (eosinofilie), vergrote limfknope en ander liggaamsorgane aangetas (geneesmiddelreaksie met eosinofilie en sistemiese simptome, ook bekend as DRESS of geneesmiddel-hipersensitiwiteitsindroom)
- Verhoogde gevoeligheid van die vel vir sonlig of UV-lig (sien ook afdeling 2, Waarskuwings en voorsorgmaatreëls)
- Skerp afgebakende, eritemateuse kolle met/sonder blase wat binne 'n paar uur na toediening van moksifloksasien ontwikkel en genees met post-inflammatoriese oorblywende hiperpigmentasie; dit verskyn gewoonlik weer op dieselfde plek op die vel of slymvlies by herblootstelling aan moksifloksasien
- Spierswakheid, gevoeligheid of pyn, en veral as jy terselfdertyd sleg voel, 'n hoë koors of donker urien het. Hierdie simptome kan veroorsaak word deur abnormale spierafbraak, wat lewensgevaarlik kan wees en tot nierprobleme ('n toestand genoem rabdomiolise) kan lei

Die volgende newe-effekte is meer dikwels waargeneem by pasiënte wat binneaars en daarna oraal behandel was:

- Verhoogde gammaglutamieltransferase ('n lewerensiem in die bloed), abnormale vinnige hartritme, lae bloeddruk, edeem (swelling van die hande, voete, enkels, lippe, mond of keel), antibiotikum-geassosieerde kolitis (erge diarree wat bloed en/of slym bevat), toevalle (aanvalle), hallusinasies, verswakking en versaking van niere.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van MOXIFLOXACIN FRESENIUS te verskaf.

Gesondheidsorgverskaffers word gevra om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com, en by die betrokke medisyne se regulatoriese owerheid in die land waarin die produk bemark word.

5. Hoe om MOXIFLOXACIN FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 30 °C in die oorspronklike verpakking en beskerm teen lig (hou sakke in hul omhulsels totdat dit benodig word vir gebruik). Moenie onder 15 °C bewaar nie. By temperature onder 15 °C kan neerslag voorkom, wat weer sal oplos by kamertemperatuur (15 °C tot 25 °C). Dit word dus aanbeveel dat die infusie nie in die yskas bewaar word nie. Beskerm teen lig. Hou die flexibags in die omhulsel/sak, of die bottels in die kartonhouers totdat dit benodig word vir gebruik.

MOXIFLOXACIN FRESENIUS moet voordat dit toegedien word eers visueel ondersoek word vir deeltjies. Slegs helder oplossings sonder deeltjies moet gebruik word.

6. Inhoud van die pakkie en ander inligting

Wat MOXIFLOXACIN FRESENIUS bevat

Die aktiewe bestanddeel is moksifloksasien. Elke sak/bottel bevat 400 mg moksifloksasien (as hidrochloried).

Die ander bestanddele is: Natriumasetaat-trihidraat, dinatriumsulfaat, water vir inspuiting, swaelsuur (vir pH-instelling). (Kyk afdeling "MOXIFLOXACIN FRESENIUS bevat natrium").

Hoe MOXIFLOXACIN FRESENIUS lyk en inhoud van die pakkie

MOXIFLOXACIN FRESENIUS is 'n deursigtige, geel oplossing.

Twee verpakkings word aangebied:

- 300 mL Poli-olefiensakke **(Free*flex*®)** sakke met 'n polipropileenpoort, verseël in 'n aluminiumfoelie buitesak.

- Die ***KabiPac***® verpakkingstelsel bestaan uit 'n primêre houer van 250 mL laedigtheid poliëtileen blaas-vul-seëlbottel. Die houer se kop word beskerm deur bedekking met 'n sekondêre verpakking wat uit HDPE/LDPE bestaan.

Verpakkingsgroottes: 1, 10, 20, 25 en 40.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Erf 7, Growthpoint Business Park

Tonettistraat 162

Halfway House extension 7

Midrand

Gauteng

1685

Telefoonnommer: (011) 545 0000

Hierdie inligtingsblad was voorheen hersien op

06 Augustus 2024

Registrasienommer

49/20.1.1/0675

Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.