**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

**LEVOFLOXACIN 5 mg/mL (100 mL) FRESENIUS solution for infusion**

**Levofloxacin**

**Sugar free.**

**Read all of this leaflet carefully before you are given LEVOFLOXACIN 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 LEVOFLOXACIN FRESENIUS is and what it is used for
2. What you need to know before you are given LEVOFLOXACIN FRESENIUS
3. How to receive LEVOFLOXACIN FRESENIUS
4. Possible side effects
5. How to store LEVOFLOXACIN FRESENIUS
6. Contents of the pack and other information.


## 1. What LEVOFLOXACIN FRESENIUS is and what it is used for

LEVOFLOXACIN FRESENIUS is an antibiotic which is used to treat various bacterial infections in adults such as sinus and lung infections, urinary tract infections and skin infections, when the oral route is not suitable.

## 2. What you need to know before you are given LEVOFLOXACIN FRESENIUS

**LEVOFLOXACIN FRESENIUS should not be given to you:**

- if you had a previous allergic reaction to levofloxacin or to other similar medicines called quinolones, or to any of the ingredients of LEVOFLOXACIN FRESENIUS (listed in section 6)
- if you have epilepsy or a history of seizures
- if you have a history of tendon disorders associated with previous fluoroquinolone antibiotic use
- if you are a child or growing adolescent under the age of 18 years
- if you are pregnant or breastfeeding
- if you have problems with your heart valves, unless no safer alternate antibiotic is available, has failed or is not well tolerated.

**Warnings and precautions**

**Tell your doctor or healthcare provider before being given the injection:**

**Take special care with LEVOFLOXACIN FRESENIUS:**

- if you are prone to seizures e.g. if you have a central nervous system disorder
- if you are taking any of the medicines mentioned under "**Other medicines and LEVOFLOXACIN FRESENIUS**"
- if you experienced serious side effects in the past when using medicines called quinolones or fluoroquinolones
- if you experience serious allergic (hypersensitivity) reactions – see "**If any of the following happens, stop receiving LEVOFLOXACIN FRESENIUS and tell your doctor immediately**"
- if you develop severe, persistent and/or bloody loose stools during or after treatment with LEVOFLOXACIN FRESENIUS, including several weeks after treatment
- if you experience symptoms of tendinitis, e.g. painful swelling and inflammation especially of the Achilles tendon which is the connective tissue that connects the calf

muscle to the heel. Tell your doctor if you are elderly, have reduced kidney function, had an organ transplant or are taking corticosteroids (cortisone and similar medicines), because the risk of tendinitis and a torn tendon is higher. If you experience any tendon problems while, shortly after or even months after receiving LEVOFLOXACIN FRESENIUS, tell your doctor immediately and rest the affected limb to avoid tendon damage

- if you have a mental illness
- if you have kidney problems, as your doctor might need to adjust the dose of LEVOFLOXACIN FRESENIUS
- if you have liver problems
- if you suffer from any other infections
- if you have porphyria, as LEVOFLOXACIN FRESENIUS may increase the chances of a porphyria attack
- if you have a muscle disorder called myasthenia gravis
- if you have electrolyte disturbances such as low blood levels of potassium or magnesium
- if you have low blood pressure or high blood pressure
- if you have heart problems or a family history of heart problems
- if you are elderly and/or if you are a woman, as you may be more sensitive to medicines that may affect the heart
- if you have Turner syndrome, a genetic disorder that affects girls and women
- if you have connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome
- if you have Behcet’s disease, a rare disorder that causes blood vessel inflammation throughout your body
- if you have Takayasu arteritis or giant cell arteritis, diseases that cause inflammation in your blood vessels
- if you have atherosclerosis, a thickening or hardening of your blood vessels

- if you have rheumatoid arthritis, a disease affecting your immune system
- if you have Sjögren's syndrome, a disorder of your immune system
- if you have a genetic disorder that affects your red blood cells, called glucose-6-phosphate dehydrogenase deficiency, as you may be prone to bleeding problems while receiving LEVOFLOXACIN FRESENIUS
- if you are diabetic and are receiving treatment with an oral hypoglycaemic agent (e.g. glibenclamide) or insulin, as you may experience disturbances in blood sugar levels such as very low or high blood sugar
- if you experience problems with your vision or eyes, consult an eye specialist immediately
- if you are exposed to excessive sunlight or sun beds, as you may experience skin sensitivity reactions while receiving LEVOFLOXACIN FRESENIUS
- if you have to test for opiates (prescription painkillers or illegal drugs) in your urine, as treatment with LEVOFLOXACIN FRESENIUS may cause false positive results
- if you are undergoing tuberculosis (TB) testing, as treatment with LEVOFLOXACIN FRESENIUS may cause false negative results
- if you are treated for MRSA infections because of the high level of resistance
- if you are having nausea, feeling generally unwell, have severe discomfort or on-going pain or worsening pain in the stomach area or vomiting – see a doctor straight away as this could be a sign of an inflamed pancreas (acute pancreatitis).
- if you start experiencing sudden involuntary jerks, twitches of the muscles or muscle contractions - see a doctor straight away as this could be signs of myoclonus. Your doctor may need to stop treatment with levofloxacin and to start an appropriate treatment.
- if you are experiencing fatigue, skin pale, bruising, uncontrolled bleeding, fever, sore throat and serious deterioration of your general condition, or a feeling that your resistance to infection may be decreased - see a doctor straight away as this could be

signs of blood disorders. Your doctor should monitor your blood with blood counts. In case of abnormal blood counts, your doctor may need to stop treatment.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given LEVOFLOXACIN FRESENIUS.

**Children and adolescents**

Do not give LEVOFLOXACIN FRESENIUS to children or growing adolescents under the age of 18 years (see "**LEVOFLOXACIN FRESENIUS should not be given to you**").

**Other medicines and LEVOFLOXACIN FRESENIUS**

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

Please tell your doctor or other healthcare provider if you are taking any of the following medicines as they may interact with LEVOFLOXACIN FRESENIUS:

- Theophylline - used in the management of asthma.
- Non-steroidal anti-inflammatory pain medicines such as fenbufen.
- Corticosteroids - used to treat rheumatoid arthritis, inflammatory bowel disease (IBD), asthma, allergies and other conditions.
- Medicines used to treat diabetes such as glibenclamide or insulin.
- Medicines used to treat heartburn such as probenecid and cimetidine.
- Ciclosporin – used to suppress the immune system in organ transplants and to treat certain skin conditions.
- Medicines used for blood thinning such as warfarin.
- Medicines used for irregular heartbeat.
- Medicines used to treat depression, called tricyclic antidepressants.
- Medicines used to treat certain mental disorders, called antipsychotics.

- Certain antibiotics, called macrolides.

**Pregnancy and breastfeeding**

You should not receive LEVOFLOXACIN FRESENIUS if you are pregnant or breastfeeding (see "**LEVOFLOXACIN FRESENIUS should not be given to you**").

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 healthcare provider for advice before LEVOFLOXACIN FRESENIUS is given to you.

**Driving and using machines**

LEVOFLOXACIN FRESENIUS may cause drowsiness, dizziness, a feeling of movement or spinning, or vision problems (see "**Possible side effects**") and may impair your ability to concentrate and react. Please take care before driving or using machinery.

It is not always possible to predict to what extent LEVOFLOXACIN FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LEVOFLOXACIN FRESENIUS affects them.

**LEVOFLOXACIN FRESENIUS contains sodium**

LEVOFLOXACIN FRESENIUS contains 3,54 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0,2 % of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to receive LEVOFLOXACIN FRESENIUS

You will not be expected to give yourself LEVOFLOXACIN FRESENIUS. It will be given to you by a person who is qualified to do so.

You will receive LEVOFLOXACIN FRESENIUS through a needle placed into a vein. Your doctor will decide on the appropriate dose of LEVOFLOXACIN FRESENIUS depending on the type of infection you have and if you have any other medical conditions.

**If you receive more LEVOFLOXACIN FRESENIUS than you should**

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

**If you forget to receive LEVOFLOXACIN FRESENIUS**

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

## 4. Possible side effects

LEVOFLOXACIN FRESENIUS may have side effects.

Not all side effects reported for LEVOFLOXACIN FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving LEVOFLOXACIN FRESENIUS, please consult your healthcare provider for advice.

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

- Allergic (hypersensitivity) reactions including itching, skin rash, hives, angioedema (swelling of the face, lips, tongue or throat), fever, low blood pressure (dizziness), cough or other lung symptoms, difficulty breathing, shock (cold, clammy skin, irregular breathing, weakness, anxiety).
- Restlessness, nervousness, trembling or shaking, anxiety, changes in mood, self-endangering behaviour including suicidal thoughts or suicide attempt, hallucinations, paranoia, seizures or fits, brain disease, confusion, coma.
- Fainting.

- Severe, persistent and/or bloody loose stools.
- Liver problems such as loss of appetite, jaundice (yellowing of the skin and the whites of the eyes), dark urine, itchy skin, tender abdomen, severe liver injury, sudden liver failure, hepatitis.
- Dangerously low blood sugar levels, coma.
- Heart problems including sudden stomach, chest or back pain, difficulty breathing, irregular, fast or pounding heartbeat, swelling of the stomach, legs or feet, heart attack.
- Nausea, feeling generally unwell, discomfort or pain in the stomach area or vomiting. These could be signs of an inflamed pancreas (acute pancreatitis). See section 2.

These are all very serious side effects. If you have them, you may have had a serious reaction to LEVOFLOXACIN FRESENIUS. You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following:**

***Frequent side effects:***

- Sleep disturbances including trouble sleeping.
- Headache.
- Dizziness.
- A feeling of movement or spinning (vertigo).
- Inflammation of a vein.
- Nausea, vomiting, diarrhoea and stomach or abdominal cramps.
- Increases in liver enzymes.
- Pain or reddening of the skin where the injection is given.

***Less frequent side effects:***

- Tendon problems, e.g. painful swelling and inflammation especially of the Achilles tendon which is the connective tissue that connects the calf muscle to the heel.
- Fungal or other infections including vaginal thrush.
- Abnormal reduction in the number of red blood cells, white blood cells, and blood platelets in the blood.
- Increase in blood bilirubin, a substance produced by your liver.
- A condition where your body makes too much of the hormone called antidiuretic hormone.
- Low blood sugar levels.
- Low blood pressure (dizziness) or a sudden drop in blood pressure while receiving LEVOFLOXACIN FRESENIUS.
- Depression.
- Abnormal dreams, nightmares.
- Drowsiness.
- Abnormal lack of energy, tiredness.
- Difficulty walking.
- Loss of appetite.
- Taste disturbances.
- Visual disturbances including blurred vision.
- Ringing in the ears.
- A feeling of pins and needles usually in the arms and legs, including pain, burning, tingling, numbness or weakness.
- Swelling.
- Hot flushes.
- Excessive sweating.
- Fever.
- Shortness of breath.

- Stomach pain, indigestion, gas, constipation.
- Pain in your joints (arthralgia).
- Muscle pain and weakness.
- Kidney problems including kidney stones, sudden kidney failure.
- Enlargement of one or both breasts in men because of a hormonal imbalance.

***Frequency unknown:***

- A torn tendon, e.g. of the Achilles tendon which is the connective tissue that connects the calf muscle to the heel.
- Weakness, numbness and pain usually in the hands and feet.
- Involuntary, erratic, writhing movements of the face, arms, legs or trunk.
- Muscle injury or torn muscles.
- Torn ligaments.
- Pain and inflammation in your joints (arthritis).
- Pain, including pain in back, chest, arms and legs.
- High blood sugar levels.
- Increased pressure inside the skull.
- Problems with memory, i.e. problems remembering things.
- Loss of taste.
- Smell disturbances including loss of smell.
- Temporary vision loss.
- Hearing problems, hearing loss.
- Tight chest.
- Inflammation of the pancreas which causes severe pain in the abdomen and back.
- Sensitivity to light, skin reactions when exposed to sunlight or sun beds.
- Inflamed or sore mouth.
- Attacks of porphyria in patients with porphyria.

- Bleeding problems.
- Bone marrow stops producing new blood cells, this may cause tiredness, lower ability to fight infection and uncontrolled bleeding (bone marrow failure).
- Feeling very excited, elated, agitated or enthusiastic (mania).
- Darker areas of skin (hyperpigmentation).
- Sudden involuntary jerks, twitches of the muscles or muscle contractions (myoclonus).

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

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LEVOFLOXACIN FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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 LEVOFLOXACIN FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep in outer container until required for use.

Do not refrigerate or freeze.

Use within 3 hours after perforation of the rubber stopper.

For single use. Discard unused portion.

Please return expired medicine to your pharmacist for safe disposal.

## 6. Contents of the pack and other information

### What LEVOFLOXACIN FRESENIUS contains

**The substance is** levofloxacin. Each 1 mL solution for infusion contains levofloxacin hemihydrate equivalent to 5 mg levofloxacin.

**The other ingredients are** sodium chloride, sodium hydroxide (1 M) (for pH-adjustment), hydrochloric acid 37 % (for pH-adjustment) and water for injection.

Sugar free.

### What LEVOFLOXACIN FRESENIUS looks like and contents of the pack:

Yellow to greenish yellow clear solution free from visible particles.

100 mL solution in clear, opaque LDPE bottlepack containers with one or two rubber discs inside a LDPE, HDPE or polypropylene cap tightly welded with a flange.

Packed in 1, 20 or 25 x 100 mL.

100 mL solution in overwrapped freeflex (polyolefine) bags.

Packed in 10 x 100 mL.

Not all container closure systems may be marketed.

### Holder of Certificate of Registration

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**Registration number**

45/20.1.1/0139

**Access to the corresponding Professional Information**

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

**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS: S4**

**LEVOFLOXACIN 5 mg/mL (100 mL) FRESENIUS oplossing vir infusie**

**Levofloksasien**

**Suikervry.**

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

- Hou hierdie inligtingsblad. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

**Wat is in hierdie inligtingsblad**


1. Wat is LEVOFLOXACIN FRESENIUS en waarvoor word dit gebruik
2. Wat jy moet weet voordat LEVOFLOXACIN FRESENIUS aan jou gegee word
3. Hoe om LEVOFLOXACIN FRESENIUS te bewaar
4. Moontlike newe-effekte
5. Hoe om LEVOFLOXACIN FRESENIUS te bewaar
6. Inhoud van die pakkie en ander inligting.


## 1. Wat is LEVOFLOXACIN FRESENIUS en waarvoor word dit gebruik

LEVOFLOXACIN FRESENIUS is 'n antibiotikum wat gebruik word om verskeie bakteriële infeksies by volwassenes te behandel, soos sinus- en longinfeksies, urienweginfeksies en velinfeksies, wanneer orale toediening nie geskik is nie.

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

**Jy moet nie LEVOFLOXACIN FRESENIUS ontvang nie:**

- indien jy voorheen 'n allergiese reaksie op levofloksasien of ander soortgelyke medisyne genaamd kinolone gehad het, of op enige van die bestanddele van LEVOFLOXACIN FRESENIUS (gelys in afdeling 6)
- indien jy epilepsie het of 'n geskiedenis van stuipe
- indien jy in die verlede tendonaandoenings gehad het wat met vorige gebruik van fluoorkinoloon antibiotika geassosieer was
- indien jy 'n kind of opgroeiende adolessent onder die ouderdom van 18 jaar is
- indien jy swanger is of borsvoed
- indien jy probleme met jou hartkleppe het, tensy daar geen veiliger alternatiewe antibiotika beskikbaar is nie, die middel nie gewerk het nie of nie goed verdra word nie.

**Waarskuwings en voorsorgmaatreëls**

**Lig jou dokter of gesondheidsorgverskaffer in voordat jy ingespuit word:**

**Neem spesiale voorsorg met LEVOFLOXACIN FRESENIUS:**

- indien jy geneig is tot aanvalle, bv. as jy 'n sentrale senuweestelselversteuring het
- indien jy enige van die medisyne neem wat onder "**Ander medisyne en LEVOFLOXACIN FRESENIUS** " gelys word
- indien jy in die verlede ernstige newe-effekte ervaar het toe jy medisyne genaamd kinolone of fluorokinolone gebruik het

- indien jy ernstige allergiese (hipersensitiwiteits-) reaksies ervaar – sien “**Indien enige van die volgende gebeur, hou op om LEVOFLOXACIN FRESENIUS te ontvang en lig dadelik jou dokter in**”
- indien jy tydens of na behandeling met LEVOFLOXACIN FRESENIUS, ook etlike weke na behandeling, ernstige, aanhoudende en/of bloederige, los stoelgange ervaar
- indien jy simptome van tendinitis ervaar, soos pynlike swelling en inflammasie, veral van die Achilles-tendon, die bindweefsel wat die kuitspier aan die hak vasmaak. Lig jou dokter in as jy bejaard is, verminderde nierfunksie het, 'n orgaanoorplanting gehad het, of kortikosteroïede (kortisoon en soortgelyke medisyne) neem, aangesien jy dan 'n hoër risiko het om tendinitis of 'n gebarste tendon te ontwikkel. Indien jy enige tendonprobleme tydens, kort na of selfs maande na die ontvangs van LEVOFLOXACIN FRESENIUS ondervind, lig jou dokter dadelik in en laat die aangetaste ledemaat rus om tendonskade te voorkom
- indien jy al ’n geestesiekte het
- indien jy nierprobleme het, aangesien jou dokter moontlik die dosis van LEVOFLOXACIN FRESENIUS sal moet aanpas
- indien jy lewerprobleme het
- indien jy enige ander infeksies het
- indien jy porfirie het, aangesien LEVOFLOXACIN FRESENIUS die waarskynlikheid van 'n porfirie-aanval kan verhoog
- Indien jy 'n spieraandoening, genaamd miastenie gravis het
- indien jy elektrolietversteurings soos lae kalium- of magnesiumvlakke in jou bloed het
- indien jy lae of hoë bloeddruk het
- indien jy hartprobleme het of 'n geskiedenis van hartprobleme
- indien jy bejaard is en/of as jy 'n vrou is, aangesien jy dalk meer gevoelig kan wees vir medisyne wat die hart kan beïnvloed
- indien jy Turner-sindroom het, 'n genetiese afwyking wat meisies en vroue affekteer

- indien jy bindweefselversteurings soos Marfan-sindroom of Ehlers-Danlos-sindroom het
- indien jy Behcet se siekte het, 'n seldsame aandoening wat bloedvatontsteking deur jou hele liggaam veroorsaak
- indien jy Takayasu-arteritis of reuseselarteritis het, siektes wat inflammasie in jou bloedvate veroorsaak
- indien jy aterosklerose het, 'n verdikking of verharding van jou bloedvate
- indien jy rumatoïede artritis het, 'n siekte wat jou immuunstelsel aantas
- indien jy Sjögren se sindroom het, 'n versteuring van jou immuunstelsel
- indien jy 'n genetiese afwyking het wat jou rooibloedselle aantas, genaamd glukose-6-fosfaatdehidrogenase-tekort, aangesien jy dan tydens behandeling met LEVOFLOXACIN FRESENIUS tot bloedingsprobleme geneig kan wees
- indien jy diabetes het en met 'n hipoglukemieslukmiddel (bv. glibenklamied) of insulien behandel word, aangesien jy versteurings in bloedsuikervlakke soos baie lae of hoë bloedsuiker kan ervaar
- Indien jy probleme met jou visie of oë ondervind, raadpleeg dadelik 'n oogspesialis
- indien jy aan oormatige sonlig of sonbeddens blootgestel word, aangesien jy velreaksies tydens behandeling met LEVOFLOXACIN FRESENIUS kan ervaar
- indien jy 'n toets vir opiate (pynstillers op voorskrif of onwettige dwelms) in jou urien moet laat doen, aangesien behandeling met LEVOFLOXACIN FRESENIUS vals-positiewe resultate kan veroorsaak
- indien jy tuberkulose (TB) toetse ondergaan, aangesien behandeling met LEVOFLOXACIN FRESENIUS vals-negatiewe resultate kan veroorsaak
- indien jy vir 'n MRSA-infeksie behandel word, weens die hoë vlak van weerstandigheid
- indien jy naar is, oor die algemeen ongesteld voel, erge ongemak of aanhoudende pyn of verergerende pyn in die maagarea of braking het – raadpleeg dadelik 'n dokter, aangesien dit 'n teken van 'n ontsteekte pankreas (akute pankreatitis) kan wees.

- indien jy skielike, onwillekeurige rukbewegings, spiertrekkings of spiersametrekkings ervaar, kry dadelik mediese hulp, aangesien dit tekens van mioklonus kan wees. Jou dokter sal dalk behandeling met levofloksasien moet staak en 'n geskikte behandeling begin
- Indien jy moegheid, 'n bleek vel, kneusplekke, ongekontroleerde bloeding, koors, 'n seer keel en erge agteruitgang van jou algemene toestand ervaar, of as jy voel dat jou weerstand teen infeksies verminder het, raadpleeg dadelik 'n dokter, aangesien dit tekens van bloedaandoenings kan wees. Jou dokter sal jou bloed met behulp van bloedtellings moet monitor. In geval van abnormale bloedtellings, kan dit wees dat jou dokter jou behandeling moet staak.

Indien jy nie seker is of enige van die bogenoemde op jou van toepassing is nie, praat met jou dokter, verpleegster of apteker voordat jy LEVOFLOXACIN FRESENIUS kry.

**Kinders en adolessente**

Moenie LEVOFLOXACIN FRESENIUS aan kinders of adolessente onder 18-jarige ouderdom gee nie (sien “**LEVOFLOXACIN FRESENIUS moet nie aan jou gegee word nie**”).

**Ander medisyne en LEVOFLOXACIN FRESENIUS**

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

Lig asseblief jou dokter of ander gesondheidsorgverskaffer in as jy enige van die volgende medisyne neem, aangesien hulle 'n interaksie met LEVOFLOXACIN FRESENIUS kan hê:

- Teofillien - gebruik by die beheer van asma.
- Niesteroïdale anti-inflammatoriese medisyne soos fenbufen.
- Kortikosteroïede - gebruik vir die behandeling van rumatoïede artritis, inflammatoriese

dermkanaalsiekte (IDS), asma, allergieë en ander siektetoestande.

- Medisyne gebruik vir die behandeling van diabetes, soos glibenklamied of insulien.
- Medisyne gebruik vir die behandeling van sooibrand, soos probenesied en simetidien.
- Siklosporien - gebruik vir die onderdrukking van die immuunstelsel in orgaanoorplantings en om sekere veltoestande te behandel.
- Medisyne gebruik vir bloedverdunning, soos warfarien.
- Medisyne gebruik vir onreëlmatige hartklop.
- Medisyne gebruik vir die behandeling van depressie, genaamd trisikliese antidepressante.
- Medisyne gebruik vir die behandeling van sekere geestestoestande, genaamd antipsigotiese middels.
- Sekere antibiotika, genaamd makroliede.

**Swangerskap en borsvoeding**

Jy moet nie LEVOFLOXACIN FRESENIUS ontvang as jy swanger is of borsvoed nie (kyk "**LEVOFLOXACIN FRESENIUS moet nie moet nie aan jou gegee word nie**").
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 vir advies voordat LEVOFLOXACIN FRESENIUS aan jou gegee word.

**Bestuur en die gebruik van masjinerie**

LEVOFLOXACIN FRESENIUS kan lomerigheid, duiseligheid, 'n gevoel van beweging of rondomtalie, of visuele steurnisse veroorsaak (sien "**Moontlike newe-effekte**") en kan jou vermoë om te konsentreer en te reageer, belemmer. Wees asseblief versigtig voordat jy bestuur of masjinerie gebruik.

Dit is nie altyd moontlik om te voorspel tot hoe 'n mate LEVOFLOXACIN FRESENIUS met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle nie bewus is tot hoe 'n mate LEVOFLOXACIN FRESENIUS hulle aantas nie.

**LEVOFLOXACIN FRESENIUS bevat natrium**

LEVOFLOXACIN FRESENIUS bevat 3,54 mg natrium (hoofkomponent van kook/tafelsout) in elke mL. Dit is gelykstaande aan 0,2 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

## 3. Hoe om LEVOFLOXACIN FRESENIUS te bewaar

Daar sal nie van jou verwag word om LEVOFLOXACIN FRESENIUS aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.
Jy sal LEVOFLOXACIN FRESENIUS deur 'n naald, wat in jou aar geplaas word, ontvang.
Jou dokter sal besluit watter dosis LEVOFLOXACIN FRESENIUS geskik is vir jou; dit sal afhang van die tipe infeksie wat jy het en of jy enige ander mediese toestande het.

**Indien jy meer LEVOFLOXACIN FRESENIUS ontvang het as wat jy moes**

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

**Indien jy vergeet om LEVOFLOXACIN FRESENIUS te ontvang**

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

## 4. Moontlike newe-effekte

LEVOFLOXACIN FRESENIUS kan newe-effekte hê.

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

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

- Allergiese (hipersensitiwiteits-) reaksies, insluitend jeuk, veluitslag, netelroos, angio-edeem (swelling van die gesig, lippe, tong of keel), koors, lae bloeddruk (duiseligheid), hoes of ander longsimptome, probleme met asemhaling, skok (koue, klam vel, onreëlmatige asemhaling, swakheid, angs).
- Rusteloosheid, senuweeagtigheid, bewing of bewerasie, angs, gemoedskommelings, selfbedreigende gedrag, insluitend selfdoodgedagtes of -pogings, hallusinasies, paranoia, aanvalle of stuiptrekkings, breinafwykings, verwarring, koma.
- Floute.
- Erge, volgehoue en/of bloederige los stoelgange.
- Lewerprobleme, soos verlies aan eetlus, geelsug (geel verkleuring van die vel en oogwitte), donker urien, jeukerige vel, teer buik, ernstige lewerskade, skielike lewerversaking, hepatitis.
- Gevaarlik lae bloedsuikervlakke, koma.
- Hartprobleme, insluitend skielike maag-, bors- of rugpyn, probleme met asemhaling, onreëlmatige, vinnige of kloppende hartklop, swelling van die maag, bene of voete, hartaanval.
- Naarheid, 'n algemene gevoel van ongesteldheid, ongemak of pyn in die maagarea of braking. Dit kan tekens wees van 'n ontsteekte pankreas (akute pankreatitis). Kyk afdeling 2.

Hierdie newe-effekte is almal baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige reaksie op LEVOFLOXACIN FRESENIUS hê. Jy kan dringende mediese aandag of hospitalisering benodig.

**Lig jou dokter in as jy enige van die volgende waarneem:**

***Gereelde newe-effekte:***

- Slaapversteurings insluitend slaapprobleme.
- Hoofpyn.
- Duiseligheid.
- 'n Gevoel van beweging of ronddraaiende gevoel (vertigo).
- Inflammasie van die aar.
- Naarheid, braking, diarree en maag- of buikkrampe.
- 'n Toename in lewerensieme.
- Pyn of rooi vel waar die inspuiting gegee word.

***Minder gereelde newe-effekte:***

- Tendonaandoenings, bv. pynlike swelling en inflammasie, veral van die Achilles-tendon, die bindweefsel wat die kuitspier aan die hak vasmaak.
- Swam- of ander infeksies waaronder vaginale sproei.
- Abnormale afname in die aantal rooibloedselle, witbloedselle en bloedplaatjies in die bloed.
- Toename in bloedbilirubien, 'n stof wat deur die lewer vervaardig word.
- 'n Siektetoestand waarby jou liggaam te veel van 'n hormoon genaamd antidiuretiese hormoon vervaardig.
- Lae bloedsuikervlakke.
- Lae bloeddruk (duiseligheid) of 'n skielike daling in bloeddruk terwyl jy LEVOFLOXACIN FRESENIUS ontvang.

- Depressie.
- Abnormale drome, nagmerries.
- Lomerigheid.
- Abnormale verlies aan energie, moegheid.
- Sukkel om te loop.
- Verlies aan eetlus.
- Smaakversteurings.
- Gesigsversteurings insluitend dowwe visie.
- Suising in die ore.
- 'n Naalde- en speldegevoel, gewoonlik in die arms en bene, insluitend pyn, brandgevoel, tinteling, gevoelloosheid of swakheid.
- Swelling.
- Warmgloede.
- Oormatige sweet.
- Koors.
- Kortasemigheid.
- Maagpyn, slegte spysvertering, gas, hardlywigheid.
- Pyn in jou gewrigte (artralgie).
- Spierpyn en swakheid.
- Nierprobleme, insluitend nierstene, skielike nierversaking.
- Vergroting van een of albei borste by mans weens 'n hormonale wanbalans.

***Frekwensie onbekend:***

- 'n Geskeurde tendon, bv. van die Achilles-tendon, die bindweefsel wat die kuitspier aan die hak vasmaak.
- Swakheid, gevoelloosheid en pyn gewoonlik in die hande en voete.

- Onwillekeurige, onreëlmatige, wringende bewegings van die gesig, arms, bene of die romp.
- Spierbesering of geskeurde spiere.
- Geskeurde ligamente.
- Pyn en inflammasie in jou gewrigte (artritis).
- Pyn, insluitend pyn in die rug, bors, arms en bene.
- Hoë bloedsuikervlakke.
- Verhoogde druk binne die skedel.
- Probleme met geheue, soos om te sukkel om dinge te onthou.
- Verlies van smaak.
- Reukversteurings, insluitend reukverlies.
- Tydelike sigverlies.
- Gehoorprobleme, gehoorverlies.
- Benoude bors.
- Inflammasie van die pankreas, wat erge pyn in die buik en rug veroorsaak.
- Gevoeligheid vir lig, velreaksies wanneer dit aan sonlig of sonbeddens blootgestel word.
- Ontsteekte en seer mond.
- Aanvalle van porfirie by pasiënte met porfirie.
- Bloedingsprobleme.
- Die beenmurg hou op om nuwe bloedselle te produseer; dit kan moegheid, verminderde weerstand teen infeksie en onbeheerde bloeding (beenmurgversaking) veroorsaak.
- Voel baie opgewonde, uitgelate, onrustig of entoesiasties (manie).
- Donker areas op die vel (hiperpigmentasie).
- Skielike, onwillekeurige rukbewegings, spiertrekkings of sametrekkings van die spiere (mioklonus).

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 ervaar, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van 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 LEVOFLOXACIN FRESENIUS te verskaf.

Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

## 5. Hoe om LEVOFLOXACIN FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of benede 25 °C. Beskerm teen lig.

Bewaar in die buitehouer totdat dit benodig word vir gebruik.

Moenie in 'n yskas of vrieskas plaas nie.

Gebruik binne 3 uur na perforasie van die rubberprop.

Vir eenmalige gebruik. Gooi die ongebruikte gedeelte weg.

Neem asseblief medisyne wat verval het na jou apteker vir die veilige wegdoening daarvan.

## 6. Inhoud van die pak en ander inligting

**Wat LEVOFLOXACIN FRESENIUS bevat**

**Die aktiewe bestanddeel is** levofloksasien. Elke 1 mL oplossing vir infusie bevat levofloksasienhemihidraat gelykstaande aan 5 mg levofloksasien.

**Die ander bestanddele is** natriumchloried, natriumhidroksied (1 M) (vir instelling van pH), soutsuur 37 % (vir instelling van pH), en water vir inspuiting.

Suikervry.

**Hoe LEVOFLOXACIN FRESENIUS lyk en inhoud van die pakkie:**

'n Geel tot groenerige geel, helder oplossing sonder sigbare deeltjies.

100 mL oplossing in helder, ondeursigtige LDPE-bottelverpakking met een of twee rubberskyfies in 'n LDPE-, HDPE- of polipropileendop, stewig met 'n flens vasgesweis.

Verpak in 1, 20 of 25 x 100 mL.

100 mL oplossing, omhul met freeflex (poliölefien) sakke.

Verpak in 10 x 100 mL.

Nie alle houertoemaakstelsels word bemark nie.

**Houer van die Registrasiesertifikaat**

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**Hierdie inligtingsblad is voorheen hersien in**

13 January 2026

**Registrasienommer**

45/20.1.1/0139

**Toegang tot die ooreenstemmende Professionele Inligting**

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