PATIENT INFORMATION LEAFLET

Information for the Patient about

UTIN-400 (FILM-COATED TABLETS)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

UTIN-400 containing 400 mg **norfloxacin** (Film-coated tablets).

Read all of this leaflet carefully before you start taking UTIN-400:

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **UTIN-400 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

WHAT UTIN-400 CONTAINS:

The active ingredient in **UTIN-400** is norfloxacin.

Each film-coated tablet contains 400 mg norfloxacin.

Inactive ingredients are castor oil, colloidal silicon dioxide, colourant (sunset yellow lake), croscarmellose sodium, hydroxypropyl-methylcellulose, magnesium stearate, microcrystalline cellulose, propylene glycol, talc and titanium dioxide.

WHAT UTIN-400 IS USED FOR:

UTIN-400 is an antibiotic used for the treatment of urinary tract infections.

BEFORE YOU TAKE UTIN-400:

Do NOT take UTIN-400:

- If you are allergic (hypersensitive) to norfloxacin, other quinolone antibiotics or to any of the inactive ingredients of **UTIN-400**.
- If you have impaired kidney function.
- If you have history of inflammation or irritation of tendon from using **UTIN-400** (see **"Take special care"** and **"POSSIBLE SIDE EFFECTS"**).
- If you are under the age of 18 years, as **UTIN-400** has been shown to cause damage to the joints of growing animals.
- If you are pregnant or breastfeeding your baby, as safety has not been established (see **"Pregnancy and breastfeeding"**).
- If you have mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out).

Combined use of **UTIN-400** with medicines that reduce blood pressure must be avoided in patients with impaired kidneys.

Take special care with UTIN-400:

UTIN-400 can cause severe allergic reactions (skin rash, nausea, vomiting, difficult breathing and shock) after the first dose (see **"POSSIBLE SIDE EFFECTS"**. Some reactions include heart failure, loos of consciousness, tingling, swelling in the throat and face and itching. Treatment must be discontinued when

you experiencing such reactions and contact your physician or an emergency physician who will initiate appropriate emergency measures.

Before you take **UTIN-400**, inform your doctor if you have epilepsy, a history of convulsions or seizures, or if you have been diagnosed with arteriosclerosis (build-up of plaques) of the arteries in your brain. Convulsions (seizures) have been reported with the use of **UTIN-400** (see **"POSSIBLE SIDE EFFECTS"**). **UTIN-400** may cause severe increase and serious symptoms in patients with or suspected to have mental disorders, hallucinations and/or confusion. If you experience seizures, treatment with **UTIN-400** must be stopped.

Treatment with **UTIN-400** may cause inflammation of a tendon and/or a tear in a tendon (particularly of the Achilles tendon – see **"BEFORE YOU TAKE UTIN-400"** and **"POSSIBLE SIDE EFFECTS"**), especially in older people and in those treated concurrently with corticosteroids (e.g. cortisone or prednisone). If you experience pain, swelling or redness of any tendon, immediately stop taking **UTIN-400** and rest the affected limb(s). Report to your doctor promptly. This risk may persist for several months after treatment has been stopped.

Rare cases of pain, numbness, tingling or burning and weakness affecting the arms, hands, legs or feet, decreased sense of touch, feeling abnormal unpleasant sensation when touched have been reported in patients receiving **UTIN-400** (see **"POSSIBLE SIDE EFFECTS"**). Treatment with **UTIN-400** should be stopped if you experience weakness, numbness and pain in the hands and feet, including burning, tingling, weakness, or found to have deficits in light touch,

pain, temperature, position sense, vibratory sensation in order to prevent development of an irreversible condition.

UTIN-400 may give rise to abnormal heart rhythms (see **"POSSIBLE SIDE EFFECTS"**). The use of certain other medicines (such as amiodarone, quinidine, sotalol, erythromycin and certain antidepressants, amongst others) may further increase this risk (see **"Taking other medicines with UTIN-400"**). You must immediately stop taking **UTIN-400** and report to your doctor if you experience fainting spells or palpitations. Please inform your doctor, before you start taking **UTIN-400**, if you have a personal or family history of heart rhythm disorders. Use **UTIN-400** with caution if you have heart disease such as heart failure and/or heart attack.

Elderly patients and women may be more sensitive to medicines that cause heart disease. Therefore **UTIN-400** should be used with caution in these populations (see **"HOW TO TAKE UTIN-400"**, **"Taking UTIN-400 with food and drink"** and **"If you take more UTIN-400 than you should"**).

Tell your doctor if you have been diagnosed with mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out). Your doctor will perform a thorough examination of your heart, including an echocardiogram, since **UTIN-400** should not be taken if you have mitral valve or aortic valve regurgitation (see **" Do NOT take UTIN-400"**).

UTIN-400 may affect your blood sugar (glucose) levels (see **"POSSIBLE SIDE EFFECTS"**). It may increase or decrease your blood sugar levels and is more likely to affect people that have been diagnosed with diabetes mellitus and are taking oral antidiabetic medicine(s) or are using insulin (see **"Taking other medicines with UTIN-400"**). Very high or low blood glucose levels may result in coma and death. If you have been diagnosed with diabetes mellitus, you (in conjunction with your doctor) will have to monitor your blood glucose levels carefully while you are taking **UTIN-400**. Report to your doctor if you develop excessive hunger or thirst, frequent urination, blurred vision, fatigue, sweating, shaking or trembling, or if you feel faint or dizzy.

Do not take more than one **UTIN-400** tablet (400 mg) twice daily. It is important that you drink sufficient fluids to ensure that you pass enough urine while taking **UTIN-400**.

In patients with impaired kidney function, this benefits of using **UTIN -400** must be carefully weighed for the individual (see **"HOW TO TAKE UTIN-400"**). Amounts of **UTIN-400** found in urine may be less due to impaired kidney function and since **UTIN-400** is evacuated via the kidney. Please inform your doctor if you have been diagnosed with impaired liver or kidney function, or glucose-6-phosphate dehydrogenase deficiency (an inherited disorder). People with glucose-6-phosphate dehydrogenase deficiency are more likely to develop tiredness, pallor, shortness of breath, or palpitations (due to a reduction in the number of red blood cells) while taking **UTIN-400** (see **"POSSIBLE SIDE**

EFFECTS"). Please report any of these symptoms to your doctor as soon as possible.

Combined use of **UTIN-400** with medicines that reduce high blood pressure may cause severe kidney injury in patients, especially those patients with severe renal impairment and elderly patients (see **"BEFORE YOU TAKE UTIN-400"**). Renal function should be assessed before initiating treatment, and monitored during treatment with **UTIN-400** or medicines that reduce high blood pressure.

Avoid exposure to strong sunlight or sun lamps while taking **UTIN-400**, since **UTIN-400** may increase the sensitivity of your skin to sunlight (see **"POSSIBLE SIDE EFFECTS"**). Stop taking **UTIN-400** and report to your doctor if you develop a skin rash in areas exposed to the sun (e.g. face or hands).

Inform your doctor if you have been diagnosed with myasthenia gravis, as worsening of muscle weakness has been reported with **UTIN-400**. This may be severe enough to cause life-threatening breathing difficulties (see **"POSSIBLE SIDE EFFECTS"**).

Report to your doctor if you develop stomach cramps, loose stools (diarrhoea), fever, or blood in the stool after taking **UTIN-400**, as this may be due to an infection of the large bowel which, in some instances, may become life-threatening (see **"POSSIBLE SIDE EFFECTS"**). Your doctor will prescribe appropriate treatment.

UTIN-400 has not shown to be effective in the treatment of syphilis (Sexual Transmitted Disease (STD) that causes sores in genitals). All patients with sexual transmitted disease must have serologic test (blood tests that look for proteins that fight infections in the blood) for syphilis at the time of diagnosis. Patients treated with **UTIN-400** must have a follow-up serologic test for syphilis after three months.

UTIN-400 may cause intense itching, dark urine and light-coloured bowel movements due to inflammation of liver cells (see **"POSSIBLE SIDE EFECTS"**. Patients should stop treatment and contact their doctor if signs and symptoms of inflammation of liver cells are noticed.

If vision becomes impaired or any effects on the eyes are experienced, an eye specialist must be consulted immediately.

UTIN-400 has been shown to cause inflammation of the joints in immature animals. Do not take **UTIN-400** if you are below the age of 18 years (see **"Do NOT take UTIN-400"** and **"HOW TO TAKE UTIN-400"**).

Taking UTIN-400 with food and drink:

Take **UTIN-400** with a full glass (240 mℓ) of water on an empty stomach (either 1 hour before or 2 hours after meals or milk) (see **"HOW TO TAKE UTIN-400"**).

Taking **UTIN-400** with or without alcohol may cause impairment of your ability to drive or operate machinery (see **"Driving and using machinery"**).

Pregnancy and breastfeeding:

Do not take **UTIN-400** if you are pregnant or breastfeeding your baby. **UTIN-400** has been shown to cause joint damage in animal studies (see **"Do NOT take UTIN-400"**). It is known that **UTIN-400** is excreted in human milk. In case of treatment of breast-feeding mothers with **UTIN-400**, breast-feeding must be stopped.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking UTIN-400.

Driving and using machinery:

UTIN-400 may cause you to feel dizzy and light-headed and may therefore affect your ability to drive or operate machinery. Do not drive or operate machinery until you know how **UTIN-400** affects you.

Do not take **UTIN-400** with alcohol, as your ability to drive or operate machinery may be impaired.

Taking other medicines with UTIN-400:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicine).

Please inform your doctor if you are taking any of the following medicines, as you may require a reduction in dose or special precautions:

- Medicines to treat abnormal heart rhythms (see **"Take special care with UTIN-400"**).
- Cisapride for stomach disorders, erythromycin (an antibiotic), medicines for the treatment of mental illnesses including depression (antidepressants), since these medicines may increase your risk of developing abnormal heart rhythms (see **"Take special care with UTIN-400"**).
- Nitrofurantoin (an antibiotic for urinary tract infections).
- Urinary alkalisers, such as citrates and sodium bicarbonate. Taking these medicines with **UTIN-400** may increase your risk of developing kidney stones or of injuring your kidneys.
- Antacids and multivitamins, products containing iron or zinc, and sucralphate (for stomach ulcers). These medicines may reduce the absorption of **UTIN-400** and **UTIN-400** should, therefore, be taken at least 2 hours before or after any of these medicines (see **"HOW TO TAKE UTIN-400"**).
- Didanosine for the treatment of Human Immunodeficiency Virus (HIV) infection. Didanosine should not be taken within 2 hours of taking a dose of **UTIN-400**, because it may interfere with absorption of **UTIN-400** (see **"HOW TO TAKE UTIN-400"**).
- Ciclosporin (an immune suppressant). Your doctor will need to monitor your blood levels of ciclosporin and may need to adjust your ciclosporin dose.
- Probenecid (for gout).

- Warfarin (a blood thinner) and other blood thinners. Concurrent use of **UTIN-400** may increase your chance of bleeding. Your doctor will need to monitor your prothrombin time, or perform other suitable blood clotting tests, when you are taking **UTIN-400**.
- Caffeine, clozapine (for treatment of schizophrenia), ropinirole (for Parkinson's disease), or theophylline (for chronic bronchitis or emphysema). Your doctor will need to monitor your blood levels of these medicines and you may require a dose adjustment.
- Nutritional solutions and dairy products.
- Fenbufen for the treatment of joint inflammation causing pain and stiffness.
- Clozapine/ropinirole used for the treatment of severe mental disorders known as schizophrenia.
- Glibenclamide for diabetes mellitus. It is recommended that you monitor your blood sugar levels carefully while taking **UTIN-400**, as **UTIN-400** may cause low blood sugar levels (see **"Take special care with UTIN-400"**).
- Non-steroidal anti-inflammatory drugs (NSAIDs), e.g. diclofenac or ibuprofen, for pain and fever. Please discuss this with your doctor, as use of **UTIN-400** with any of these medicines may increase the risk of developing convulsions/seizures (see **"Take special care with UTIN-400"**).
- ACE inhibitors/renin-angiotensin receptor blockers used to reduce high blood pressure.

HOW TO TAKE UTIN-400:

Do not share medicines prescribed for you with any other person.

Always take UTIN-400 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with UTIN-400 will last. Do not stop treatment early because you feel better. If you have the impression that the effect of UTIN-400 is too strong or too weak, tell your doctor or pharmacist.

For bladder infections, the usual dose is one **UTIN-400** tablet every twelve hours (twice daily) for three days. Depending on your diagnosis, your doctor may decide to treat you for longer periods of time. Your doctor will also adjust your dosage if you have impaired kidney function. It is important that you take **UTIN-400** for as long as your doctor prescribes it (i.e. finish the course of treatment).

Take **UTIN-400** with a full glass (240 mℓ) of water on an empty stomach (either 1 hour before or 2 hours after meals or milk) (see **"Taking UTIN-400 with food and drink"**).

Do not take any of the following within 2 hours of taking **UTIN-400** (see **"Taking other medicines with UTIN-400"**):

- Multivitamins.
- Products containing iron or zinc.
- Antacids containing magnesium or aluminium.
- Sucralphate (for stomach ulcers).
- Medicines containing didanosine (for treatment of HIV infection).

UTIN-400 should not be administered to children (see **"Do NOT take UTIN-400"**).

If you take more UTIN-400 than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side-effects listed below. **In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

If you forget to take UTIN-400:

Always take **UTIN-400** as prescribed. It is important that you complete the full course of treatment. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE EFFECTS:

UTIN-400 can have side-effects.

Not all side-effects reported for UTIN-400 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking UTIN-400, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **UTIN-400** and tell your doctor

immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, which may include a skin rash, difficult breathing, wheezing, hives, itching, joint or muscle pain, or swelling of the lips, face, tongue or whole body (angioedema).
- Yellow discolouration of the skin and/or whites of the eyes with or without pain over the liver area and generally feeling unwell with nausea and/or vomiting.
- Vaginal thrush (vaginal itching with a white to yellowish vaginal discharge).
- Itchy, raised, red or skin-coloured welts on the skin's surface.
- Flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters.
- Severe skin reaction that include fever, skin blisters, skin peeling, painful skin and red eyes.
- Skin disorder that includes skin or mouth lesions that a pink-red centre surrounded by a pale ring border and an outer pink-red ring.
- Painless swelling under the skin.
- Bloody or cloudy urine, fever, rash, swelling of feet or lower legs.
- Yellowed skin and eyes along with stomach pain and swelling due to liver failure.
- Fainting spells, palpitations or irregular heartbeat, light-headedness, shortness of breath with or without exercise, or coughing when lying down or chest pain (see **"Take special care with UTIN-400"**).
- Diabetic coma (life-threatening diabetes complication that causes unconsciousness).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **UTIN-400**. You may need to urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bloody or cloudy urine accompanied by fever, rash, and swelling of the feet or lower legs (interstitial nephritis).
- Seizures.
- Change in way you heart beats.
- Intense itching, dark urine and light-coloured bowel movements due to inflammation of liver cells.
- Easy bruising, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever and chills, coughing, ulcers that do not heal, or sore throat as these symptoms may be due to abnormal blood cell and platelet counts (see **"Take special care with UTIN-400"**).
- Blisters on the skin or ulcers inside the mouth.
- Dark, reddish urine, a decreased amount of urine, weakness and muscle aches.
- Decreased urine output due to kidney disease.
- Difficulty passing urine, or reduced frequency of urination.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Inflammation of one or more joints, causing pain and stiffness.
- Soreness and achiness in the muscles.

- Excessive hunger or thirst, frequent urination, blurred vision, fatique, weakness, sweating, shaking or trembling, or if you feel faint or dizzy (especially if you have been diagnosed with diabetes mellitus), since this may be due to high or low blood sugar levels and may result in coma (see **"Take special care with UTIN-400"**).
- Seeing or hearing things that are not real (hallucination), feeling of elation/euphoria.
- Convulsions/seizures, confusion, tremors, disorientation (see **"Take special care with UTIN-400"**).
- Delusions, hallucinations, talking incoherently and agitation.
- Severe stomach pain accompanied by vomiting and distension of the stomach.
- Abnormal or stomach pain or cramps, nausea, eating disorder, vomiting and diarrhoea.
- Skin rash in areas exposed to the sun (see **"Take special care with UTIN-400"**).
- Numbness, pins and needles, or a reduced sense of touch.
- Tingling and weakness starting in your feet and legs and spreading to your upper body and arms.
- Decreased sense of touch or sensation.
- Quick, involuntary muscle jerks.
- Hearing loss.
- Palpable, purple bruises on the lower legs accompanied by stomach and joint pain.
- Stomach cramps, bloody stools, fever or watery diarrhoea (loose stools)

(see **"Take special care with UTIN-400"**).

- Fever, fatigue, weight loss and muscle and joint pain due to inflammation of blood vessels.
- Pain or swelling over a tendon or tendon rupture at the back of the ankle (see **"Take special care with UTIN-400"**).
- Worsening of muscle weakness in patients with myasthenia gravis (see **"Take special care with UTIN-400"**).
- Severe lower back pain or pain in the flank with or without blood in the urine.
- Blurred vision or other visual disturbances or double vision.
- Ringing in the ears.
- Sleeplessness, nervousness, depression, agitation, sleep disturbances, anxiety, irritability, change in mood, disorientation.
- Dizziness, headache, drowsiness.
- Impaired balance or coordination due to damage in the brain, nerves or muscles.
- Tiredness.
- Loss of appetite, heartburn.
- Tearing of the eyes.
- Abnormal sense of taste.

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

STORAGE AND DISPOSING OF UTIN-400:

Store at or below 25 °C in a dry place. Protect from light. Keep well closed.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF UTIN-400:

UTIN-400 tablets are available in blister packs of 6, 10, 20 and 100 tablets.

IDENTIFICATION OF UTIN-400:

White coloured, oval shaped, uncoated tablets with biconvex faces.

REGISTRATION NUMBER OF UTIN-400:

31/20.1.1/0517

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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RSA

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