Patient Information Leaflet

SCHEDULING STATUS

S4

FLOXIN

Each tablet contains 400 mg Norfloxacin.

Sugar Free

Contains sodium:

Each tablet contains 1,709 mg sodium

Read all of this leaflet carefully before you start taking FLOXIN

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

1. What FLOXIN is and what it is used for
2. What you need to know before you take FLOXIN
3. How to take FLOXIN
4. Possible side effects
5. How to store FLOXIN
6. Contents of the pack and other information

1. WHAT FLOXIN IS USED FOR

FLOXIN contains norfloxacin. Norfloxacin is an antibiotic that works against bacteria.

FLOXIN is used to treat infections due to bacteria which are sensitive to norfloxacin.

You have been prescribed FLOXIN for the treatment of infections of the urinary system such as infection of bladder and kidney. It works by killing bacteria that can cause infections of your urinary system.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLOXIN

Do not take FLOXIN:

- If you are allergic (hypersensitive) to norfloxacin or any other ingredients of FLOXIN. (An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet or breathing difficulties)
- If you have had a reaction to a similar medicine (quinolones) in the past
- If you are suffering from disease of kidney where the kidney function is compromised.
- If you are a child or young person under the age of 18 years who is still growing.
- If you are taking blood pressure lowering medicines [angiotensin converting enzyme (ACE) inhibitors/renin angiotensin blockers) and you have impaired kidney function.
- If you have heart valve regurgitation (leaking of heart valves), unless no other safer alternative is available.
- If you are pregnant or breastfeeding.

Do not take FLOXIN if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist

Warnings and precautions

Take special care with FLOXIN

- if you have ever had fits (convulsions).
- if you have ever had an illness of nervous system.
- if you have an illness called myasthenia gravis which causes muscle weakness.

- if you or anyone in your family has anaemia caused by an illness called glucose-6-phosphate dehydrogenase deficiency (also called G-6-PD deficiency).
- if you have diabetes mellitus and are taking medication for the diabetes –You may experience change in blood glucose levels (low blood sugar/ high blood sugar).
- if you have a personal or family history of irregular heartbeat (QTc prolongation), heart problems (slow heartbeat) or low blood potassium levels.
- if you are taking any of the following medicines used to treat high blood pressure; in particular if you are elderly or have kidney problems:
    - an ACE-inhibitor
    - renin-angiotensin receptor blockers.
- if you suffer from any illness related to the liver or kidney. Your doctor may check your kidney function at regular intervals. See also information under the heading "Do not take FLOXIN".
- if you have heart valve regurgitation (leaking of heart valves). A thorough cardiovascular examination should be performed by your doctor before FLOXIN is prescribed.
- Avoid exposure to strong sunlight or sunlamps while you are taking FLOXIN.
- if you have tendon pain, particularly affecting the Achilles tendon.
- If you suffer from inflammation of the large intestine resulting in diarrhoea.
- If you develop skin eruptions or rashes (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis).
- If you develop a skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking FLOXIN.

Diarrhoea

Diarrhoea is a common problem caused by antibiotics, which usually ends when the antibiotic is discontinued. Sometimes after starting the treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two more months after having taken the last dose of the antibiotic. If this occurs, you should speak to your doctor as soon as possible.

Children and adolescents

FLOXIN is not recommended for use in children before puberty or growing adolescents.

Other medicines and FLOXIN

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

The below medications should be discussed with your doctor prior to taking FLOXIN as it may interfere with the absorption and effect of FLOXIN:

- Nitrofurantoin (antibiotic used to treat urinary infections)
- Antacids (medicines used to treat heartburn and indigestion)
- Iron preparations
- Theophylline (a medicine used to treat asthma)
- Warfarin (medicine used to prevent blood clots)
- ACE-inhibitors or renin angiotensin receptor blockers (medicines used to lower blood pressure) [see also information under the headings “Do not take FLOXIN” and “Take special care with FLOXIN”)].
- Take FLOXIN after 4 hours of taking preparations containing magnesium, aluminium, or iron salts.
- Urinary alkalisers

- Immunosuppressant medication (Ciclosporin)
- Antiretroviral medication use to treat HIV/AIDS
- Medication used to treat gout, Parkinson’s disease, diabetes and schizophrenia
- Medication used to treat pain (Non-steroidal anti-inflammatory drugs (NSAIDS)

Using FLOXIN with food and drink:

Take adequate amount of fluids while you are taking FLOXIN to ensure a proper state of hydration and adequate urinary output. If adequate amount of fluid will not be consumed, there is risk of crystals in your urine (crystalluria).

Do not take this mediation with alcohol.

Pregnancy, breast-feeding 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 healthcare provider for advice before being taking this medicine.

FLOXIN should not be used during pregnancy and breastfeeding.

Driving and using machines

The ability to drive or operate machinery may be impaired by FLOXIN, especially when alcohol is also taken.

FLOXIN contains:

Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Propylene glycol: This medicine contains 1,160 mg propylene glycol in each tablet.

3. HOW TO TAKE FLOXIN

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

Always take use FLOXIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the whole with a full glass of water. It is best to take the doses at evenly spaced times, day and night.

Your doctor will tell you how long your treatment with FLOXIN will last. If you have the impression that the effect of FLOXIN is too strong or too weak, tell you doctor or pharmacist.

If you take more FLOXIN than you should

In the event of overdosage, consult your doctor of pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLOXIN

If you do miss a dose of this medicine, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking FLOXIN

Keep taking FLOXIN until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

FLOXIN can have side effects.

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

If any of the following happens, you should stop taking FLOXIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Red skin rash or allergic reaction
- Sudden, life-threatening severe allergic reaction
- Difficulty in breathing/shortness of breath
- Sudden paralysis starting in the legs and spreading up the body (Guillian-Barré syndrome)
- Swelling of the large intestine resulting in stomach pains and diarrhoea
- Swelling of the blood vessels

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to FLOXIN. You may need 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:

- Irregular heart beat
- Ringing in the ears
- Hearing loss
- Problems relating to the heart valves
- Increased/decreased blood sugar levels
- Seizures
- Tingling/numbness sensation
- Visual disturbances

- Yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems
- Kidney disorders resulting in swelling of feet or lower legs
- Crystals in the urine

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Inability to sleep
- Nervousness
- Dizziness
- Headache
- Drowsiness
- Disorientation
- Shakes (tremors)
- Cramps
- Eating disorders
- Heartburn
- Nausea
- Vomiting
- Diarrhoea

Less frequent side effects:

- Depression
- Irritability
- False perceptions (hallucinations)
- Nerve disease affecting the extremities
- Pain in the upper abdomen

- Joint stiffness
- Increased sensitivity to sunlight

Frequency unknown side effects:

- Fungal infections affecting the vagina
- Tendon rupture
- Muscle weakness
- Swollen breast tissue in men
- Abnormal liver function tests
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FLOXIN.

5. HOW TO STORE FLOXIN

Store all medicines out of the reach children.

- Store at or below 25 ^{o}C.
- The strip packs should not be removed from the carton until required for use, to protect from light.

- Do not take FLOXIN after the expiry date stated on the pack. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT FLOXIN CONTAINS

Each tablet contains 400 mg Norfloxacin.

Sugar Free

Contains sodium:

Each tablet contains 1,709 mg sodium

The other ingredients are:

Core

- Croscarmelose sodium (Ac-di-sol),
- Magnesium stearate,
- Microcrystalline cellulose,
- Purified talc,
- Sodium lauryl sulphate.

Coating

- Hydroxypropylmethyl cellulose (5 cps),
- Polyethylene glycol 400,
- Propylene glycol,
- Purified talc,
- Titanium dioxide.

What FLOXIN looks like and the contents of the pack

White special capsule shape biconvex film coated TABLETS with breakline on one side.

6 TABLETS in aluminium strip pack:

Or one strip in one carton (i.e. 6 TABLETS per pack)

10 TABLETS in aluminium strip pack:

Or one strip in one carton (i.e. 10 TABLETS per pack)

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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