APPROVED PATIENT INFORMATION LEAFLET

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LOXIP 250 mg (Tablet)

LOXIP 500 mg (Tablet)

Read all of this leaflet carefully before you start taking LOXIP.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- **LOXIP** 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.

1. WHAT LOXIP CONTAINS

The active substance is ciprofloxacin hydrochloride.

LOXIP 250 mg TABLETS: Each film-coated tablet contains ciprofloxacin hydrochloride equivalent to 250 mg ciprofloxacin.

LOXIP 500 mg TABLETS: Each film-coated tablet contains ciprofloxacin hydrochloride equivalent to 500 mg ciprofloxacin.

The other ingredients are cellulose, microcrystalline; sodium starch glycollate; povidone; silica, colloidal anhydrous and magnesium stearate and opadry white.

Opadry white contains hypromellose, macrogol and titanium dioxide (C.I. No: 77891).

2. WHAT LOXIP IS USED FOR

LOXIP is used for the treatment of the following infections due to sensitive micro-organisms:

- Lower respiratory tract infections
- Urinary tract infections
- Skin and soft tissue infections
- Gastro-intestinal infections such as infective diarrhoea
- Bone Infections
- Gonorrhoea

3. BEFORE YOU TAKE LOXIP

Do not take LOXIP:

- If you are hypersensitive (allergic) to ciprofloxacin hydrochloride or to other quinolones or to any of the other ingredients of **LOXIP.**
- If you are pregnant or breast-feeding.
- If you are under the age of 18 years.

Take special care with LOXIP:

- If you have a history of fits.
- If you experience crystals in your urine which causes kidney pain or discomfort when passing urine. You should be well hydrated and avoid excessive alkalinity of the urine when taking **LOXIP**.
- Long-term or repeated use of **LOXIP** can lead to superinfections with resistant bacteria or fungi.
- If you have a heart condition and/or are taking medicines for your heart, you will have to be closely monitored by your doctor.
- If you have a serious allergic reaction when taking **LOXIP** you should report to your doctor immediately.
- If you experience severe and persistent diarrhoea during or after your treatment, you should consult your doctor as soon as possible.
- If you experience painful swelling of your tendons, you should avoid any physical exercise and your doctor should be consulted.
- You should avoid direct exposure to excessive sunlight and UV-light.
- You should inform your doctor if you are taking any other medicines.
- If you are diabetic and/or are taking medicines for your blood sugar levels, you will have to be closely monitored by your doctor.

LOXIP should be swallowed whole with plenty of liquid and can be taken with or without food.

Pregnancy and Breast-feeding:

Safety of **LOXIP** in pregnant and breast-feeding women has not been established.

If you are pregnant or breast-feeding, please consult your doctor, pharmacist or healthcare professional for advice before taking this medicine.

You should not use **LOXIP** if you are pregnant, trying to become pregnant or breast-feeding your baby.

Driving and using machinery:

The ability to drive a motor vehicle or operate machinery may be affected by **LOXIP**. This applies particularly in combination with alcohol.

Taking other medicines with LOXIP:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **LOXIP** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

LOXIP interacts with theophylline typically used in the treatment of asthma, NSAIDs (e.g. ibuprofen), the immune suppressant agent cyclosporin, warfarin used as a blood thinning agent, the antidiabetic medicine glibenclamide, probenecid used for treating gout and metoclopramide used for treating nausea.

LOXIP should be administered 1 - 2 hours before, or at least 4 hours after taking iron preparations, antacids containing magnesium, aluminium, calcium or sucralfate, as interference with absorption may occur.

Please notify your doctor that you are using **LOXIP**. If you are undergoing TB tests, **LOXIP** may interfere with the test.

4. HOW TO TAKE LOXIP

Always take **LOXIP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **LOXIP** is too strong or too weak, talk to your doctor or pharmacist.

Dosage and Duration of Treatment:

The dosage range is 250 - 750 mg twice daily. The duration of treatment depends upon the severity of the infection, clinical response and bacteriological cultures.

If you take more LOXIP than you should:

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 LOXIP:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

LOXIP can have side effects.

If any of the following symptoms occur, stop taking the **LOXIP** and tell your doctor immediately.

- Tendon rupture or swelling of the tendon (tendinitis) -Tendons are tough cords of tissue that connect muscles to bones. Symptoms of tendon problems may include: Pain, swelling, tears and inflammation of tendons including the back of the ankle (achilles), shoulder, hand, or other tendon sites
- Myasthenia gravis (a type of muscle weakness) - **LOXIP** may cause worsening of myasthenia gravis symptoms, including muscle weakness, joint pain, joint swelling and general feeling of weakness.
- Severe diarrhoea with bleeding or mucus.

- If you are diabetic and have any of these symptoms: tiredness, dizzy, palpitations, excessive sweating, trembling or shaking and blurred vision.

And also the following symptoms need urgent medical attention:

- Serious skin allergic reactions including rashes, itching skin, hives and sensitivity to sunlight (blisters, sensation of skin burning), small, pin-point bleeding under the skin, redness of the skin due to allergic reactions and a red rash caused by hypersensitivity to a medicine, disease or other allergen
- Increased risk of sunburn
- Severe heart rhythm abnormalities, irregular heart beat
- Troubles associated with the nervous system such as dizziness, seizures, sense things that are not there (hallucinations), restlessness, tremors, feel anxious or nervous, confusion, depression, trouble sleeping, nightmares, suicidal thoughts or acts.

Other side effects that you may experience include:

- double vision, colour disturbances
- ringing sound in the ears, loss of hearing, impaired hearing, vertigo, feeling of constant movement of self or surroundings; sensation of spinning.
- Bruising, nose-bleeds, bleeding gums
- Frequent infections of the nose, throat, skin and other organs.
- Pale skin, mucosal linings and nail bed, feelings of weakness and fatigue.
- Headache, taste disorders
- Kidney problems such blood in the urine, crystals in the urine causing pain during urination.
- Pancreatitis (swelling and inflammation of the pancreas) causing sever upper abdominal burning pain that spreads to your back, nausea and vomiting.

Frequency Unknown

A serious skin reaction may occur known as (DRESS) Drug reaction with eosinophilia and systemic symptoms which may cause a serious skin reaction that may affect one or more organs).You may experience the following fever, severe rash, peeling skin, swelling of the face, swollen lymph

glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine.

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

6. STORING AND DISPOSING OF LOXIP

Store all medicines out of reach of children.

Store below 30 °C.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF LOXIP

LOXIP 250 mg:

Blister pack: 6's – Each carton contains 1 blister of 6 tablets each.

Tablets are packed in clear 250 microns PVC coated with 60 gsm PVdc and 25 microns printed Aluminium foil. One blister contains 6 tablets.

Blister pack: 10's – Each carton contains 1 blister of 10 tablets each.

Tablets are packed in clear 250 microns PVC coated with 60 gsm PVdc and 25 microns printed Aluminium foil. One blister contains 10 tablets.

HDPE container: 100's – Each container contains 100 tablets.

Tablets are packed in milky-white, opaque, wide mouth round 80 ml HDPE Container with 43 mm PP closure with induction sealing wad. Each container contains 100 tablets. *No dessicant is included in the container*.

LOXIP 500 mg:

Blister pack: 10's – Each carton contains 1 blister of 10 tablets each.

Tablets are packed in clear 250 microns PVC coated with 60 gsm PVdc and 25 microns printed Aluminium foil. One blister contains 10 tablets.

HDPE container: 10's- Each container contains 10 tablets. Tablets are packed in milky-white, opaque, wide mouth round 40 ml HDPE container with 33 mm PP closure with induction sealing wad. Each container contains 10 tablets. No desiccant is included in the container.

HDPE container: 100's – Each container contains 100 tablets.

Tablets are packed in milky-white, opaque, wide mouth round 140 ml HDPE Container with 43 mm PP closure with induction sealing wad. Each container contains 100 tablets. *No dessicant is included in the container*.

8. IDENTIFICATION OF LOXIP

LOXIP 250 mg:

White to off-white, round shaped, film coated tablets, with a score line on one side and debossed with 'F' and '23' with a score line in between on the other side.

LOXIP 500 mg:

White to off-white, capsule shaped, film coated tablets, with a score line on one side and debossed with 'F 22' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

LOXIP 250 mg (Tablet): 41/20.1.1/1052

LOXIP 500 mg (Tablet): 41/20.1.1/1053

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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