PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FLOPRO 250 mg TABLETS (Tablet)

FLOPRO 500 mg TABLETS (Tablet)

FLOPRO 750 mg TABLETS (Tablet)

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **FLOPRO** 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 FLOPRO CONTAINS

The active substance is ciprofloxacin hydrochloride.

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

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

FLOPRO 750 mg TABLETS: Each film-coated tablet contains ciprofloxacin hydrochloride equivalent to 750 mg ciprofloxacin.

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

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

2. WHAT FLOPRO IS USED FOR

FLOPRO 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 FLOPRO

Do not take FLOPRO:

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

Take special care with FLOPRO:

- 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 **FLOPRO**.
- Long-term or repeated use of **FLOPRO** 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 **FLOPRO** 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 a diabetic patient receiving concurrent treatment with an oral medicine to lower your blood glucose or insulin. Disturbances in blood glucose including too high and too low blood glucose levels have been reported. Your doctor will carefully monitor your blood glucose level.

Taking FLOPRO with food and drink:

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

Pregnancy and Breastfeeding:

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

Safety of **FLOPRO** in pregnant and breastfeeding women has not been established.

You should not use **FLOPRO** if you are pregnant, trying to become pregnant or breastfeeding your baby.

Driving and using machinery:

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

Important information about some of the ingredients of FLOPRO:

FLOPRO is sugar free.

Taking other medicines with FLOPRO:

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

FLOPRO 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.

FLOPRO 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 **FLOPRO**. If you are undergoing TB tests, **FLOPRO** may interfere with the test.

4. HOW TO TAKE FLOPRO

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

Always take **FLOPRO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dosage range is 250 - 750 mg twice daily.

If you have the impression that the effect of **FLOPRO** is too strong or too weak, talk to your doctor or pharmacist.

If you take more FLOPRO 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 FLOPRO:

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

FLOPRO can have side effects.

If any of the following symptoms occur, stop taking the **FLOPRO** 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) - **FLOPRO** 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.
- Low blood sugar, particularly in diabetic patients.
- High blood sugar, low blood sugar coma.

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.

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

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

6. STORING AND DISPOSING OF FLOPRO

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep bottles tightly closed.

Keep blisters in outer carton until required for use.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF FLOPRO

FLOPRO 250 mg TABLETS:

Blister pack:

Tablets are packed in blisters that are comprised of silver aluminium foil and clear PVC/PVdC.

Pack size: 6's- Each blister strip contains 6 tablets. 1 blister strip containing 6 tablets is packed in a cardboard carton.

Pack size: 10's- Each blister strip contains 10 tablets. 1 blister strip containing 10 tablets is packed in a cardboard carton.

HDPE container pack:

Pack size: 10's

Tablets are packed in a white, opaque, wide mouth round 40 ml HDPE container with a white opaque 33 mm PP closure with induction sealing wad. No desiccant is included in the container. The HDPE container is packed in a cardboard carton.

Pack size: 100's

Tablets are packed in a milky-white, round 80 ml HDPE container with a white opaque 43 mm PP closure with induction sealing wad. No desiccant is included in the container. The HDPE container is packed in a cardboard carton.

FLOPRO 500 mg TABLETS:

Blister pack:

Tablets are packed in blisters that are comprised of silver aluminium foil and clear PVC/PVdC.

Pack size: 10's- Each blister strip contains 10 tablets. 1 blister strip containing 10 tablets is packed in a cardboard carton.

HDPE container pack:

Pack size: 100's

Tablets are packed in a milky-white, opaque, wide mouth round 140 ml HDPE container with a white opaque 43 mm PP closure with induction sealing wad.

No desiccant is included in the container. The HDPE container is packed in a cardboard carton.

FLOPRO 750 mg TABLETS:

Blister pack:

Tablets are packed in blisters that are comprised of silver aluminium foil and clear PVC/PVdC.

Pack size: 10's- Each blister strip contains 10 tablets. 1 blister strip containing 10 tablets is packed in a cardboard carton.

HDPE container pack:

Pack size: 100's

Tablets are packed in a milky-white, opaque, wide mouth round 200 ml HDPE container with a white opaque 45 mm PP closure with induction sealing wad.

No desiccant is included in the container. The HDPE container is packed in a cardboard carton.

8. IDENTIFICATION OF FLOPRO

FLOPRO 250 mg TABLETS:

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.

FLOPRO 500 mg TABLETS:

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.

FLOPRO 750 mg TABLETS:

White to off-white, capsule shaped, film-coated tablets debossed with ‘C’ on one side and ‘93’ on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

FLOPRO 250 mg TABLETS (Tablet): 45/20.1.1/0198

FLOPRO 500 mg TABLETS (Tablet): 45/20.1.1/0199

FLOPRO 750 mg TABLETS (Tablet): 45/20.1.1/0200

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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