PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM:

SANDOZ LEVOFLOXACIN 250 (film-coated tablets)

SANDOZ LEVOFLOXACIN 500 (film-coated tablets)

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read again.
- If you have further questions, do not hesitate to ask your pharmacist or doctor.
- This medicine has been only prescribed for you, therefore, it should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT SANDOZ LEVOFLOXACIN CONTAINS:

- The active substance is 250 or 500 mg levofloxacin hemihydrate equivalent to 250 mg or 500 mg levofloxacin.

- The other ingredients are croscarmellose sodium, ethanol*, glycerol dibehenate, lactose monohydrate, povidone, sodium starch glycolate, talc and coating substances.

*Ethanol evaporates during manufacture and is not included in the final product.

Each Sandoz Levofloxacin 250 tablet contains sugar (lactose monohydrate 13,27 mg).

Each Sandoz Levofloxacin 500 tablet contains sugar (lactose monohydrate 26,54 mg).

2. WHAT IS SANDOZ LEVOFLOXACIN USED FOR:

This medicine is used to help fight infections in the treatment of bronchitis, pneumonia, pyelonephritis, sinusitis, complicated and uncomplicated urinary tract infections, complicated and uncomplicated skin structure infections as well as intra-abdominal infections.

3. BEFORE YOU TAKE SANDOZ LEVOFLOXACIN:

Do not take SANDOZ LEVOFLOXACIN if you:

- Are allergic (hypersensitive) to levofloxacin, any flouroquinolone or any of the ingredients of SANDOZ LEVOFLOXACIN.
- Are younger than 18 years of age.
- Are pregnant or breastfeeding.

- Have epilepsy.
- Have a history of tendon disorders related to fluoroquinolone use.

Take special care with SANDOZ LEVOFLOXACIN tablets if you have any other medical problems, especially:

- Renal impairment.
- Patients predisposed to seizures.
- Photosensitive.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your pharmacist, doctor or any health professional for advice.

Taking SANDOZ LEVOFLOXACIN with food:

SANDOZ LEVOFLOXACIN can be taken with or without food.

Important information about some of the ingredients of SANDOZ LEVOFLOXACIN:

SANDOZ LEVOFLOXACIN contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare

hereditary conditions of lactose/fructose or galactose intolerance should not take SANDOZ LEVOFLOXACIN.

Driving and operating machines:

Do not drive and operate any tools or machines because SANDOZ LEVOFLOXACIN may lead to dizziness, drowsiness, anxiety or confusion.

Taking other medicines with SANDOZ LEVOFLOXACIN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of SANDOZ LEVOFLOXACIN may lead to undesirable problems. Please consult your pharmacist, doctor or healthcare professional, for advice.

The following medicines may have bad interactions with SANDOZ LEVOFLOXACIN:

- Antacids containing calcium, magnesium, aluminium, or ferrous sulfate, sucralfate or zinc may reduce SANDOZ LEVOFLOXACIN absorption.
- Anti-arrhythmic agents may cause some heart problems.
- Anti-diabetic agents.
- Anti-inflammatory agents increase the risk of central nervous system stimulation and fits.

- Cimetidine or probenecid.

4. HOW TO TAKE SANDOZ LEVOFLOXACIN:

Always take SANDOZ LEVOFLOXACIN tablets exactly as your pharmacist or doctor has instructed you. Always check with your health professionals if you are unsure. The usual dose is:

- 500 mg once daily for 5 to 10 days for bronchitis, bacterial exacerbations.
- 500 mg once or twice daily for 10 to 14 days for pneumonia.
- 500 mg once daily for 10 days for sinusitis.
- 250 mg once daily for 3 days for uncomplicated urinary tract infections.
- 250 mg once daily for 10 days for complicated urinary tract infections.
- 250 to 500 mg once daily for 7 to 10 days for uncomplicated skin and skin structure infections.
- 500 mg once daily for 10 to 14 days for complicated skin and skin structure.
- 500 mg once daily for 10 to 14 days for abdominal infections.

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

Do not chew.

Do not share medicines prescribed for you with others.

If you take more SANDOZ LEVOFLOXACIN than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take SANDOZ LEVOFLOXACIN:

If you miss a dose of this medicine, take it as soon as possible. However, if it almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. DO NOT take a double dose to make up for the forgotten individual doses.

You are advised to NEVER stop your SANDOZ LEVOFLOXACIN before the course is completed, even if your symptoms have disappeared.

5. POSSIBLE SIDE EFFECTS:

SANDOZ LEVOFLOXACIN can have side effects, not all side effects reported for this medicine are included in this leaflet.

If any of the following happen, stop taking SANDOZ LEVOFLOXACIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe diarrhea (if severe or bloody consult your doctor immediately).
- Disturbances of muscular co-ordination, hallucinations, convulsions and psychotic reactions such as restlessness, agitation, anxiety, depression and confusion.

- Skin rash.
- Tendonitis (inflammation of a tendon).
- Swelling of skin e.g. mouth.
- Allergic reactions such as anaphylactic-like shock.
- Nervousness.

Other side effects may occur that usually do not need medical attention. These side effects may go way during treatment as your body adjust to the medicine.

Tell your doctor if you notice any of the following:

- Loss of appetite.
- Nausea.
- Vomiting.
- Headache.
- Dizziness.
- Sleep disturbances.

Should your general health worsen, please consult your doctor, pharmacist or health professional for advice.

6. STORING AND DISPOSING OF SANDOZ LEVOFLOXACIN:

Do not store above 25 ^{0}C. Store in a dry place.

Do not store in bathrooms and expose the tablets to the sun.

Store in original package.

Do not use after expiry date stated on the carton.

Do not dispose of unused medicine in drains or sewerage systems. Return them to your doctor or pharmacist.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF SANDOZ LEVOFLOXACIN:

Sandoz Levofloxacin 250 mg film-coated tablets are packed in PVC/TE/PVDC/Al blister packs of 3 or 5 tablets. One side of the blister pack is transparent and the other side is silver coloured.

Sandoz Levofloxacin 500 mg film-coated tablets are packed in PVC/TE/PVDC/Al blister packs of 3 or 5 tablets. One side of the blister pack is transparent and the other side is silver coloured.

8. IDENTIFICATION OF SANDOZ LEVOFLOXACIN:

Sandoz Levofloxacin 250 are light orange-pink in colour, octagonal, biconvex, film coated tablets and scored on both sides.

Sandoz Levofloxacin 500 are light orange-pink in colour, octagonal, biconvex, film coated tablets and scored on one side.

9. REGISTRATION NUMBER:

Sandoz Levofloxacin 250: A40/20.1.1/0525

Sandoz Levofloxacin 500: A40/20.1.1/0526

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Sandoz SA (Pty) Limited[1]

72 Steel Road

Kempton Park 1619

South Africa

11. DATE OF PUBLICATION:

Date of registration: 06 October 2006

Date of most recent approval of patient information leaflet: 17 April 2009

[1] Company Reg. No.: 1990/001979/07