

PATIENT INFORMATION LEAFLET FOR
CIPLADANTIN

SCHEDULING STATUS:

S4

CIPLADANTIN 50 & 100 (capsules)**Nitrofurantoin****Contains sugar:****[CIPLADANTIN 50]: Lactose monohydrate 81 mg per capsule.****[CIPLADANTIN 100]: Lactose monohydrate 162 mg per capsule.****Read all of this leaflet carefully before you start using CIPLADANTIN**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care professional.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See **section 4**)
- CIPLADANTIN 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 is CIPLADANTIN and what is used for:
2. What you need to know before you take CIPLADANTIN.
3. How to take CIPLADANTIN.
4. Possible side effects .
5. How to store CIPLADANTIN.
6. Contents of the pack and other information.

1. What is CIPLADANTIN and what it is used for

CIPLADANTIN is an antibiotic.

It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

2. What you need to know before you take CIPLADANTIN**Do not take CIPLADANTIN:**

- If you are hypersensitive (allergic) to CIPLADANTIN or any of the ingredients of CIPLADANTIN listed in **section 6**.
- If you have kidney disease or impaired kidney function.
- If you are in the final stages of pregnancy.
- You suffer from a blood disorder called porphyria.
- If you have a glucose 6-phosphate dehydrogenase (G6PD) deficiency, a blood disorder that can lead to anaemia.

- If you are a nursing mother of an infant with a deficiency of glucose 6-phosphate dehydrogenase.

Do not give CIPLADANTIN to babies under the age of three months.

Warnings and precautions

Tell your doctor if you are suffering from any of the following:

- Kidney impairment.
- Asthma or a history of asthma attacks
- Diabetes (too much sugar in your blood).
- Anaemia (decreased red blood cells condition indicated by pallor and feeling faint).
- Salt imbalances in your body.
- Vitamin B deficiency.
- Liver impairment.

The above conditions may increase the chance of developing a side effect which results in damage to the nerves, causes altered sense of feeling, pins and needles.

- if you lack an enzyme (body chemical) called glucose-6-phosphate dehydrogenase, which causes your red blood cells to be more easily damaged.
- if you have any disease of the lungs, liver or nervous system. If you need to take CIPLADANTIN Capsules for a number of months, your doctor may want to regularly check how your lungs and liver are working.

- as this medicine may interfere with urine tests for glucose, causing the test to give a “false positive” result. That is, the test may say that glucose is present in the urine even if it is not.

This medicine may also cause your urine to turn yellow or brown.

- If you experience fatigue, yellowing of the skin or eyes, itching, skin rashes, joint pain, abdominal discomfort, nausea, vomiting, loss of appetite, dark urine, and pale or gray-colored stools. It may be symptoms of liver disorder.

You may experience other health complications due to the use of CIPLADANTIN. Consult your doctor if any of the following happen while on treatment with CIPLADANTIN:

- Asthma, coughing or respiratory-related problems.
- Liver impairment/disease including hepatitis, these may be indicated yellowing of the skin and eyes.
- Kidney impairment, signs may include decreased urine output, fatigue and swelling in the legs or feet.
- Feeling weak/faint and being pale, this could be due to blood disorders.

Other medicines and CIPLADANTIN

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

Tell your doctor if you are taking any of the following:

- Probenecid (used to treat gout)
- Sulphinpyrazone (used to treat gout)
- The antacid, magnesium trisilicate
- Antibiotics such as nalidixic acid and oxolinic acid
- Medicines that reduce the acid in the urine (urine alkalisers) such as potassium citrate
- Carbonic anhydrase inhibitors such as acetazolamide (medicines for altitude sickness and eye problems)
- Food and medicines (like hyoscine for easing bloatedness and relief of stomach pain) delaying gastric emptying
- Oral contraceptives
- Oral typhoid vaccine

CIPLADANTIN with food and drink

CIPLADANTIN must be taken with food or milk to minimise gastrointestinal (gut) side effects.

Pregnancy and breastfeeding

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 taking CIPLADANTIN.

Do not take CIPLADANTIN if you are in your last weeks of pregnancy (from 38 weeks).

Do not take CIPLADANTIN if you are breastfeeding a baby who is still under three months of age.

Driving and using machines

CIPLADANTIN can cause dizziness and therefore may impair your ability to drive vehicles or operate machinery. You need to be aware of how CIPLADANTIN affects you before you engage in such activities.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CIPLADANTIN

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

Always take CIPLADANTIN exactly as described in this leaflet or as your doctor or pharmacist or nurse told you. Check with your doctor, pharmacist or nurse if you are not sure.

Always take CIPLADANTIN with food or milk.

Adults

Treating urinary infections: the usual dose is one tablet of [CIPLADANTIN 50] or [CIPLADANTIN 100] four times a day.

Preventing recurrences: the usual dose is one tablet of [CIPLADANTIN 50] or [CIPLADANTIN 100] once daily.

Children

Your doctor will determine the right dose for you (or your child) based on weight.

If you take more CIPLADANTIN than you should

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

If you forget to take CIPLADANTIN

Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

CIPLADANTIN can have side effects.

Not all side effects reported for CIPLADANTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLADANTIN, please consult your health care provider for advice.

If any of the following happens, stop taking CIPLADANTIN and tell your doctor

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Skin eruptions characterised painful red blisters with a flu-like illness (due to a life-threatening condition called Steven-Johnson syndrome)
- Rash (may be reddish)
- Itching
- Inability to breathe
- Yellowing of the skin and eyes, may be accompanied by abdominal pain or swelling (may be a sign of liver disease or impairment)

These are all very serious side effects. If you have them, you may have had a serious reaction to CIPLADANTIN. 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:
- Lung problems such as breathlessness, coughs and asthma attacks
- Genito-urinary infections like vaginal thrush
- Anaemia (lack of red blood cells, symptoms include fainting and pallor)
- Collapsing

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

Tell your doctor if you notice any of the following:

Less frequent side effects

- Dizziness

- Headache
- Drowsiness
- Bluish colour of the skin (e.g. visibly in your hands), this is due to lack of oxygen in your body.

Side effects with unknown frequencies

- Anorexia
- Nausea
- Vomiting
- Abdominal (stomach) pain
- Diarrhoea
- Yellow or brown urine
- Lack of energy
- Fever
- Joint pain
- Depression
- Intense excitement and happiness
- Confusion
- Psychotic reactions (hallucinations, delusions)

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, 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 CIPLADANTIN.

You may also report any suspected side effects (to Cipla Medpro (Pty) Ltd) by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

5. How to store CIPLADANTIN

Store at or below 25 °C in the original pack, away from light and moisture.

The blisters should not be removed from the carton until required for use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information**What CIPLADANTIN contains**

Each capsule contains 50 mg or 100 mg CIPLADANTIN in macrocrystalline form, a synthetic chemical of controlled crystal size.

Inactive ingredients:

- Hard gelatin capsule

- Lactose monohydrate
- Maize starch
- Purified talc
-

The gelatin capsule is composed of:

- Gelatin
- Iron oxide yellow
- Sodium dodecyl sulfate
- Titanium oxide
- Water

Black ink is used for printing on the gelatin capsule is made up of:

- Black iron oxide
- Butyl alcohol
- Dehydrated alcohol
- Isopropyl alcohol
- Potassium hydroxide
- Propylene glycol
- Purified water
- Shellac
- Strong ammonia solution

What CIPLADANTIN looks like and contents of the pack

White, opaque NC-coated Alu/PVC blister containing 10 capsules each.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in

Not applicable

Registration number/s

CIPLADANTIN 50: 53/18.5/0109.107

CIPLADANTIN 100: 53/18.5/0110.108

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.
--