1.3.2 PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start receiving ADCO CIPROFLOXACIN 2 mg/ml as it contains important information.

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

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

SCHEDULING STATUS: **S4**

PROPRIETARY NAME (and dosage form)

ADCO CIPROFLOXACIN 2 mg/ml Infusion (Parenteral)

WHAT ADCO CIPROFLOXACIN 2 mg/ml CONTAINS:

ADCO CIPROFLOXACIN 2 mg/ml contains 2 mg ciprofloxacin per ml in 0,9 % sodium chloride solution.

List of inactive ingredients: Lactic acid, Water for injections.

Sugar free

WHAT ADCO CIPROFLOXACIN 2 mg/ml IS USED FOR:

ADCO CIPROFLOXACIN 2 mg/ml is used in adults to treat severe and/or complicated bacterial infection of the lungs, bladder, gut (diarrhoea), bone, or skin and soft tissues where other antimicrobials used for similar infections were considered not to be an appropriate treatment option, have failed,

cannot be used or are not tolerated. It is used to prevent you getting an infection caused by a bacterium called *Neisseria meningitidis.*

ADCO CIPROFLOXACIN 2 mg/ml is also indicated for the following infections

- Enlargement of prostate gland
- Sexually transmitted diseases

ADCO CIPROFLOXACIN 2 mg/ml is to be given only by or under the immediate supervision of your doctor.

BEFORE TAKING ADCO CIPROFLOXACIN 2 mg/ml:

Do not receive ADCO CIPROFLOXACIN 2 mg/ml if:

- **You or your child are under 18 years old**.
- Persons with a known hypersensitivity to the above listed ingredients or quinolones.
- If you have previously experienced side effects with the use of quinolone/fluoroquinolone antibiotics relating to your joints, muscles, ligaments, nerves, central nervous system (brain), epilepsy or mental health (psychiatric disorder)
- If you were born with or have any condition with abnormal heart rhythm whether related to QT time prolongation or not (seen on ECG, electrical recording of the heart)
- If you are taking other medicines that result in an abnormal heart rate and/or rhythm tracing (ECG) e.g. (prolongation of “QT time”).
- If you have an enlargement or “bulge” of a large blood vessel (aortic aneurysm) or a previous episode of aortic dissection (a tear in the aortic wall) or a family history of aortic aneurysm/dissection or other risk factors or existing predisposing conditions)
- If you have mitral valve and /aortic valve regurgitation

- If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis)
- If you are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin receptor blockers. Ask your doctor if you are unsure.

Take special care with ADCO CIPROFLOXACIN 2 mg/ml:

Do not use in patients with a history of convulsive disorders seizure or fit. (see **DO NOT RECEIVE ADCO CIPROFLOXACIN 2 mg/ml**)

- If you are currently taking other medicines that can reduce your blood potassium levels
- If you have a family history of aortic aneurysm or aortic dissection or other risk factors or existing predisposing conditions (e.g. connective tissue disorders such as Marfan Syndrome, Vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure or known atherosclerosis (see DO NOT RECEIVE **ADCO CIPROFLOXACIN 2 mg/ml**)
- **ADCO CIPROFLOXACIN 2 mg/ml** may interfere with the interpretation of diagnostic cultural tests for tuberculosis

Pregnancy and breast-feeding:

- Safety during pregnancy and breast-feeding your baby has not been established.
- You should not use ADCO CIPROFLOXACIN 2 mg/ml during pregnancy or when breastfeeding your baby

If you are pregnant or breast feeding your baby, please consult your healthcare provider for advice before taking this medicine.

Driving or using machinery:

- The ability to drive or operate machinery may be impaired.

Taking other medicines with ADCO CIPROFLOXACIN 2mg/ml:

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

Do not take ciprofloxacin with the following:

- Theophylline
- Non-steroidal anti-inflammatory fenbufen
- Warfarin
- Glibenclamide
- Probenecid
- Methotrexate (for certain types of cancer, psoriasis, arthritis)
- Phenytoin
- If you are on treatment with ACE inhibitors/angiotensin receptor blockers used to control your blood pressure. Ask your doctor if you are not sure.

HOW TO USE ADCO CIPROFLOXACIN 2 mg/ml:

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

Adults: 100 mg to 200 mg every twelve hours. For severe and/or complicated infections 400 mg may be administered every 12 hours.

ADCO CIPROFLOXACIN 2 mg/ml IV should be administered by intravenous infusion over a period of 60 minutes. Slow infusion into a large vein will minimise patient discomfort and reduce the risk of venous irritation. The infusion solution can be infused directly.

If you take more ADCO CIPROFLOXACIN 2 mg/ml then you should (an overdose):

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of over-dosage your doctor will manage the over-dosage.

Only a small amount of ciprofloxacin (< 10 %) is removed from the body after haemodialysis or peritoneal dialysis.

Treatment is symptomatic and supportive.

POSSIBLE SIDE-EFFECTS:

ADCO CIPROFLOXACIN 2 mg/ml can have side effects.

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

If any of the following happens, stop receiving **ADCO CIPROFLOXACIN 2 mg/ml** and tell your doctor immediately:

Swelling of the face, lips, tongue, throat and airways (breathing tubes), difficult breathing, blueness of the skin, low blood pressure, heart failure and can result in death.

The following are possible side effects:

Gastrointestinal disorders [stomach and intestines]:

- Nausea, diarrhoea, vomiting, heartburn, indigestion, stomach pain, excessive amount of gas in the stomach, lack of appetite, impaired taste.

Nervous system disorders:

- Dizziness, headache, tiredness, nervousness, agitation, trembling
- Impaired smell

Eye disorders:

- Visual disturbances

Ear disorders:

- Ringing in the ears

Skin disorders:

- Sensitive to light
- Skin rashes

Muscle disorders:

- Pain

- Swelling

Kidney, bladder and liver disorders

Heart and blood vessel disorders

- Sudden severe pain in your chest, abdomen (tummy) or back.

The ability to drive a motor vehicle or operate machinery may be impaired by ADCO CIPROFLOXACIN 2 mg/ml. This applies particularly in combination with alcohol.

Long-term or repeated administration of **ADCO CIPROFLOXACIN 2 mg/ml** can lead to superinfections with resistant bacteria or fungi.

STORING AND DISPOSAL OF ADCO CIPROFLOXACIN 2 mg/ml:

Store at or below 25 °C. Protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not administer the solution if visible particles are present, or if the solution is cloudy. The solution must be infused immediately after opening and any portion remaining after infusion must be discarded. **ADCO CIPROFLOXACIN 2 mg/ml** may not be refrigerated or frozen.

Do not use after the expiry date stated on the packaging.

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

PRESENTATION OF ADCO CIPROFLOXACIN 2 mg/ml:

50 ml clear and colourless PVC infusion bag containing 50 ml solution.

100 ml clear and colourless PVC infusion bag containing 50 ml or 100 ml solution.

250 ml clear and colourless PVC infusion bag containing 200 ml solution.

The bags are over-pouched with an aluminium-polyester over-wrapping.

IDENTIFICATION OF ADCO CIPROFLOXACIN 2 mg/ml:

A clear, pale yellow solution free from visible particles.

REGISTRATION NUMBER:

A39/20.1.1/0646

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE REGISTRATION CERTFICATE:

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg, 2013

P.O. Box 6888, Johannesburg, 2000

Customer Care: 0860 ADCOCK/232625

DATE OF PUBLICATION:

Date of registration: 07 April 2006

Date amended: 24 April 2020 (Clinical unit and PV unit recommendation)