PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ADCO METRONIDAZOLE 500 mg/100 ml Infusion (Parenteral)

Read all of this leaflet carefully before you are given ADCO METRONIDAZOLE

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

Active ingredient:

Each 100 ml solution contains 500 mg metronidazole.

Inactive ingredients:

Citric acid monohydrate BP or citric acid anhydrous BP, sodium phosphate BP (dodecahvdrate), sodium chloride BP, 10 % citric acid, sodium phosphate dodecahydrate 10 % solution, water for injection.

Sugar free

WHAT ADCO METRONIDAZOLE IS USED FOR

ADCO METRONIDAZOLE is an antibiotic and anitprotozoal medicine used for the treatment of infections that are caused by bacteria or parasites.

It is used either alone or along with other antimicrobial medicines to treat infections of the intestines, pelvis, appendix and wounds.

BEFORE YOU ARE GIVEN ADCO METRONIDAZOLE

You should not be administered ADCO METRONIDAZOLE:

- If you are hypersensitive (allergic) to metronidazole or any of the other ingredients of **ADCO METRONIDAZOLE**
- If you have blood dyscrasias (blood disorder)
- If you suffer from active diseases of the central nervous system
- If you are pregnant or breastfeeding

Special care should be taken with ADCO METRONIDAZOLE:

- If you have liver disease including liver disease caused by alcohol
- If you have kidney disease or kidney failure

Receiving ADCO METRONIDAZOLE with food and drink:

Alcohol should not be consumed during treatment with **ADCO METRONIDAZOLE** due to the possibility of a disulfiram-like reaction which will cause hypersensitivity to the unpleasant and toxic effects of alcohol. These effects include nausea, vomiting, flushing, dizziness, headache, chest and abdominal discomfort and general hangover-like symptoms.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

ADCO METRONIDAZOLE is contraindicated in pregnancy and lactation.

Driving and using machinery:

You may experience drowsiness or dizziness therefore do not drive or operate any tools or machinery.

Taking other medicines with ADCO METRONIDAZOLE:

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

- If you are on any anti-hypertensive medicine (medicines used to treat high blood pressure), your dose may need to be reduced while on treatment with **ADCO METRONIDAZOLE**.
- If you are taking warfarin or other oral anticoagulants (blood thinners or medicines used to prevent blood clots), your dose may need to be reduced.
- If you are taking phenobarbitone (medicine used to treat fits or difficulty sleeping), your dose of **ADCO METRONIDAZOLE** may need to be increased.

HOW TO RECEIVE ADCO METRONIDAZOLE

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

ADCO METRONIDAZOLE is an injection and will be administered into your vein. You will not be expected to give yourself **ADCO METRONIDAZOLE**. It will be administered to you by a healthcare provider.

If you are given more ADCO METRONIDAZOLE than you should:

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

If you missed a dose of ADCO METRONIDAZOLE:
Do not receive a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS
ADCO METRONIDAZOLE can have side effects.

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

If any of the following happens, stop receiving **ADCO METRONIDAZOLE** and tell your doctor immediately:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ADCO METRONIDAZOLE**. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- weakness, numbness, pain and a tingling sensation in your hands and feet
- nervous system disorder with disturbances of muscular co-ordination, difficulty in movement, including walking
- weakness
- dizziness
- sleeplessness
- depression
- confusion

These are all serious side effects that may occur when receiving **ADCO METRONIDAZOLE** at high doses or for prolonged treatment. You may need urgent medical attention. The use of **ADCO METRONIDAZOLE** should be stopped if neurological side effects are noted.

Tell your doctor if you experience any of the following:

- nausea
- headache
- unpleasant metallic taste
- loss of appetite

- vomiting
- diarrhoea
- abdominal cramps
- dry mouth
- dry vagina
- furred tongue
- swelling or soreness of the tongue
- inflammation of oral mucosa
- temporary moderate low numbers of all types of white blood cells in your blood (the signs include infections of the mouth, gums, throat and lungs)
- raised liver enzyme values
- skin rashes
- severe itching of the skin
- skin rash with red, raised, itchy bumps
- inflammation of the bladder, pain when urinating and urgency
- darkening of urine
- inflammation of a vein after intravenous administration

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

STORING AND DISPOSING OF ADCO METRONIDAZOLE

Store all medicines out of reach of children. Store at or below 25 ºC.

Protect from direct sunlight.

PRESENTATION OF ADCO METRONIDAZOLE

ADCO METRONIDAZOLE 500 mg/100 ml is supplied in a 100 ml Viaflex® plastic bag.

IDENTIFICATION OF ADCO METRONIDAZOLE

A clear, bright, pale-yellow solution.

REGISTRATION NUMBERS

27/20.2.6/0562

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Critical Care (Pty) Ltd
1 Sabax Road,
Aeroton,
Johannesburg,
2013
+27 11 494 8000

DATE OF PUBLICATION

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Namibia: NS2 17/20.2.6/0086

PIL 04 September 2018

ADCO METRONIDAZOLE 500 mg/100 ml

PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS S4

EIENDOMSNAAM, KONSENTRASIE EN FARMASEUTIESE VORM

ADCO METRONIDAZOLE 500 mg/100 ml Infusie

(Parenteraal)

Lees die hele voubiljet noukeurig deur voordat ADCO METRONIDAZOLE aan u gegee word

- Bewaar hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- **ADCO METRONIDAZOLE** is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul simptome dieselfde as u.

WAT ADCO METRONIDAZOLE BEVAT

Aktiewe bestanddeel:

Elke 100 ml oplossing bevat 500 mg metronidasool.

Onaktiewe bestanddele:

Sitroensuurmonohidraat BP of watervrye sitroensuur BP, natriumfosfaat BP (dodekahidraat), natriumchloried BP, 10 % sitroensuur, natriumfosfaatdodekahidraat 10 % oplossing, water vir inspuiting.

Suikervry

WAARVOOR ADCO METRONIDAZOLE GEBRUIK WORD

ADCO METRONIDAZOLE is 'n antibiotika en antiprotozoale medisyne wat gebruik word vir die behandeling van infeksies wat deur bakterieë of parasiete veroorsaak word.

Dit word óf alleen óf saam met ander antimikrobiese medisyne gebruik om infeksies van die ingewande, bekken, blindederm en wonde te behandel.

ADCO METRONIDAZOLE 500 mg/100 ml

VOORDAT ADCO METRONIDAZOLE AAN U GEGEE WORD

ADCO METRONIDAZOLE moet nie aan u toegedien word nie:

- Indien u hipersensitief (allergies) is vir metronidasool of enige van die ander bestanddele van **ADCO METRONIDAZOLE**
- Indien u bloeddiskrasieë (bloedversteuring) het
- Indien u aan aktiewe siektes van die sentrale senuweestelsel ly
- Indien u swanger is of borsvoed.

Spesiale sorg moet geneem word met ADCO METRONIDAZOLE:

- Indien u lewersiekte het, insluitend lewersiekte wat deur alkohol veroorsaak word
- Indien u niersiekte of nierversaking het.

Gebruik van ADCO METRONIDAZOLE saam met kos en drank:

Alkohol moet nie gedrink word tydens behandeling met **ADCO METRONIDAZOLE** nie weens die moontlikheid van 'n disulfiraam-agtige reaksie wat hipersensitiwiteit vir die onaangename en toksiese effekte van alkohol sal veroorsaak. Hierdie effekte sluit in naarheid, braking, blosing, duiseligheid, hoofpyn, bors- en abdominale ongemak en algemene babalaas-tipe simptome.

Swangerskap en borsvoeding:

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u hierdie medisyne gebruik.

ADCO METRONIDAZOLE is teenaangedui tydens swangerskap en laktasie.

Bestuur van ‘n voertuig en gebruik van masjinerie:

U kan lomerigheid of duiseligheid ervaar, daarom moet u nie ‘n voertuig bestuur of enige gereedskap of masjinerie hanteer nie.

Neem van ander medisyne saam met ADCO METRONIDAZOLE:

Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

- Indien u enige antihipertensiewe medisyne gebruik (medisyne wat gebruik word om hoë bloeddruk te behandel), sal u dosis dalk verminder moet word terwyl u met **ADCO METRONIDAZOLE** behandel word.
- Indien u warfarien of ander orale antikoagulante neem (bloedverdunners of medisyne wat gebruik word om bloedklonte te voorkom), moet u dosis dalk verminder word.
- Indien u fenobarbitoon neem (medisyne wat gebruik word om stuipaanvalle of slaapprobleme te behandel), moet u dosis **ADCO METRONIDAZOLE** dalk verhoog word.

HOE OM ADCO METRONIDAZOLE TE ONTVANG

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

ADCO METRONIDAZOLE is 'n inspuiting en sal in u aar toegedien word. Daar sal nie van u verwag word om **ADCO METRONIDAZOLE** aan uself toe te dien nie. Dit sal deur 'n gesondheidsorg kundige aan u toegedien word.

Indien u meer ADCO METRONIDAZOLE ontvang as wat u moes:

Aangesien 'n gesondheidsorg kundige hierdie medisyne sal toedien, sal hy/sy die dosis beheer. In die geval van oordosis sal u dokter egter die oordosis hanteer.

Indien u 'n dosis ADCO METRONIDAZOLE gemis het:

Moenie 'n dubbele dosis ontvang om vergete individuele dosisse in te haal nie.

MOONTLIKE NEWE-EFFEKTE

ADCO METRONIDAZOLE kan newe-effekte hê.

Nie alle newe-effekte wat vir **ADCO METRONIDAZOLE** aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige nadelige effekte ervaar terwyl u hierdie medisyne gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, hou op om **ADCO METRONIDAZOLE** te ontvang en lig u dokter dadelik in:

- swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- uitslag of jeuk
- flou word

Dit is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op **ADCO METRONIDAZOLE** gehad. U benodig dalk dringende mediese hulp.

Vertel u dokter dadelik as u enige van die volgende opmerk:

- swakheid, gevoelloosheid, pyn en 'n tintelende sensasie in u hande en voete.
- senuweestelselafwyking met versteurings van spierkoördinasie, probleme met beweging, insluitend om te loop
- swakheid
- duiseligheid
- slapeloosheid

- depressie
- verwarring

Dit is alles ernstige newe-effekte wat kan voorkom wanneer **ADCO METRONIDAZOLE** teen hoë dosisse of vir langdurige behandeling ontvang word. U benodig dalk dringende mediese hulp. Die gebruik van **ADCO METRONIDAZOLE** moet gestaak word indien neurologiese newe-effekte opgemerk word.

Lig u dokter in indien u enige van die volgende ervaar:

- naarheid
- hoofpyn
- onaangename metaalsmaak
- verlies aan eetlus
- braking
- diarree
- abdominale krampe
- droë mond
- droë vagina
- harige tong
- swelling of seerheid van die tong
- inflammasie van mondslymvlies
- tydelike matige lae getalle van alle soorte witbloedselle in u bloed (die tekens sluit infeksies van die mond, tandvleis, keel en longe in)
- verhoogde lewerensiemwaardes
- veluitslag
- erge jeuk van die vel
- veluitslag met rooi, opgehewe, jeukerige knoppe
- ontsteking van die blaas, pyn tydens urinering en dringendheid
- verdonkering van urien
- inflammasie van 'n aar na binneaarse toediening.

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

ADCO METRONIDAZOLE 500 mg/100 ml

BERGING EN WEGDOENING VAN ADCO METRONIDAZOLE

Bêre alle medisyne buite bereik van kinders. Bêre teen of benede 25 ºC.

Beskerm teen direkte sonlig.

AANBIEDING VAN ADCO METRONIDAZOLE

ADCO METRONIDAZOLE 500 mg/100 ml word in 'n 100 ml Viaflex® plastiekhouer verskaf.

IDENTIFIKASIE VAN ADCO METRONIDAZOLE

'n Deurskynende, helder, liggeel oplossing.

REGISTRASIENOMMERS

27/20.2.6/0562

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Adcock Ingram Critical Care (Edms) Bpk

Sabaxweg 1,

Aeroton,

Johannesburg,

2013

+27 11 494 8000

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