1.3.2 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.

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, vomitting, 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 (medicnes used to treat high blood pressure), your dose may need to be redcued 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 doasage. However, on 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 container.

IDENTIFICATION OF ADCO METRONIDAZOLE

A clear, bright, pale yellow solution.

REGISTRATION NUMBERS

27/20.2.6/0562

NA: NS2 17/20.2.6/0086

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

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