AXCEL METRONIDAZOLE TABLET

Metronidazole (200mg, 400mg)

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What Axcel Metronidazole Tablet is used for

Axcel Metronidazole Tablet is used to treat certain infections caused by bacteria and other organisms in different parts of the body.

How Axcel Metronidazole Tablet works

Axcel Metronidazole Tablet is an antibiotic that belongs to a group of medicines called nitroimidazoles. This medicine works by killing or stopping the growth of bacteria and other organisms causing these infections.

Before you use Axcel Metronidazole Tablet

– When you must not use it

Do not take Axcel Metronidazole Tablet if you have ever had an allergic reaction to:

- Metronidazole or any other nitroimidazoles.
- Any of the ingredients listed at the end of this leaflet

Do not take Axcel Metronidazole Tablet if:

- You have or have had a blood disorder
- You have or have had a disease of the brain, spinal cord or nerves.

- Before you start to use it

You must tell your doctor if you have any allergies to any other medicines

or any other substances such as foods, preservatives or dyes.

Tell your doctor if you have or have ever had any health problems/medical conditions including:

- A blood disorder.
- Disease of the brain, spinal cord or nerves
- You drink alcohol

Please consult your doctor before start to use Axcel Metronidazole tablet if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Axcel Metronidazole tablet against the benefits they expect it will have for you.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Axcel Metronidazole Tablet or may affect how well it works. These include:

- Alcohol
- Disulfiram, a medicine used to treat chronic alcohol dependence.
- Warfarin or other medicines used to prevent blood clots.
- Phenytoin, a drug used to treat convulsions.
- Lithium, a medicine used to treat manic depressive illness and some other types of depression.
- Phenobarbitone, a medicine for convulsions or sedation
- Cimetidine, a medicine used to treat gastric reflux and ulcers.

How to use Axcel Metronidazole Tablet

-How much to use

For oral administration only.

Follow all directions given to you by your doctor and pharmacist carefully. The dose will vary from patient to patient. Your doctor will decide the right dose for you.

- When to use it

Your doctor will decide when it is appropriate for you to take Axcel Metronidazole Tablet according to the type of condition you have.

- How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.
- Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

- If you forget to use it

• Do not double up the dosage as Axcel Metronidazole Tablet may give you unacceptable side effects.

- If you use too much (overdose)

• It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Axcel Metronidazole Tablet too much.

While you are using it

– <u>Things you must do</u>

- Tell all doctors, dentists and pharmacists who are treating you that you are taking Axcel Metronidazole Tablet.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Metronidazole Tablet according to the recommended dosage.
 - Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

- Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

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 Do not drink alcohol or any alcoholic drinks while taking Axcel Metronidazole Tablet.

- Things to be careful of

 This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Axcel Metronidazole Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- Gastrointestinal discomfort
- Nausea
- Diarrhea
- Epigastric distress and abdominal cramping
- Headache
- Vomiting.
- Strange taste in mouth
- Dizziness, feeling of incoordination or uncoordinated movements
- Depression
- Skin rashes
- Dry mouth, dryness of the mouth (or vagina or vulva)
- Unusual urination patterns (e.g. difficulty in passing urine)
- Reduce your white blood cell
- Other side effects not listed above may also occur in some patients. Tell your doctor as soon as possible if you notice any other effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting).

Storage and disposal of Axcel Metronidazole Tablet

-<u>Storage</u>

Keep Axcel Metronidazole Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

– <u>What it looks like</u>

Axcel Metronidazole-200 Tablet White biconvex, round tablet, 9.8mm in diameter.

Axcel Metronidazole-400 Tablet Elongated white tablet, 18.8mm in diameter.

-<u>Ingredients</u>

Active Ingredient (s): Metronidazole

Inactive Ingredients:

Aerosil, Sodium Starch Glycollate, Povidone, Lactose, Microcrystalline Cellulose, Corn Starch, Purified Water, Dioctyl Sodium Sulphosuccinate, Isopropyl Alcohol, Magnesium Stearate and Opadry White.

-MAL Number

Axcel Metronidazole-200 Tablet MAL20032263AZ

Axcel Metronidazole-400 Tablet MAL19872225AZ

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

Date of revision

04/01/2016

Serial number

BPFK(R4/1)081215/00483