

DYNIDAZOL TABLET

Metronidazole (200mg, 400mg)

What is in this leaflet

1. What DYNIDAZOL TABLET is used for
2. How DYNIDAZOL TABLET works
3. Before you use DYNIDAZOL TABLET
4. How to use DYNIDAZOL TABLET
5. While you are using it
6. Side effects
7. Storage and Disposal of DYNIDAZOL TABLET
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What DYNIDAZOL TABLET is used for

Metronidazole is used in the treatment and prevention of certain bacterial infections.

How DYNIDAZOL TABLET works

This medicine works by killing or stopping the growth of protozoa and bacteria. It also has a radiosensitising effect on hypoxic tumour cells.

Before you use DYNIDAZOL TABLET

- When you must not use it

Do not take DYNIDAZOL TABLET if you have hypersensitivity to Metronidazole.

Pregnancy and lactation

Do not take DYNIDAZOL TABLET if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take DYNIDAZOL TABLET if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Tell your doctor or pharmacist if:

- Blood disorder
- Active disease of the central nervous system
- Severely impaired liver function

- Taking other medicines

Tell your doctor if you are under:

- Alcohol usage
- Warfarin-type oral anticoagulants treatment
- Lithium treatment (for depressive disorders)
- Phenobarbitone treatment (to control seizures)
- Phenytoin treatment (to control

seizures)

- Cimetidine treatment (relieve heartburn)

Inform your doctor if you are affected by Cockayne syndrome.

Cases of severe liver toxicity or acute liver failure in patients with Cockayne syndrome have been reported with product containing Metronidazole.

Stop taking Dynidazol Tablet and tell your doctor immediately if you develop: stomach pain, decreased appetite, nausea, vomiting, fever, unusual tiredness, yellowing of the skin & whites of the eyes, dark-coloured urine, light or clay-coloured stools or itching.

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

How to use DYNIDAZOL TABLET

- How much to use

All to be taken with or after food

To treat bacterial infection:

Adults: 400 to 800 mg three times daily by mouth for 5 to 10 days.

Children:

1 to 3 years: May be given one-quarter,
3 to 7 years: One-third,
7 to 10 years: One-half the adult dose;
alternatively 35 to 50 mg per kg body-weight daily in divided doses has been suggested.

Your doctor will work out how much your child should take depending on their weight.

To prevent infection from happening after surgery:

Adults: 400 mg every 8 hours for 3 to 4 days, followed postoperatively by intravenous or rectal administration until oral therapy is possible.

Children: Your doctor will work out how much your child should take depending on their weight

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking DYNIDAZOL TABLET for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause dizziness, headache, and gastrointestinal disturbance such as nausea, vomiting, diarrhoea, stomach pain or cramps.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking DYNIDAZOL TABLET.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give DYNIDAZOL TABLET to anyone else, even if they have the same symptoms or condition as you.

DYNIDAZOL TABLET

Metronidazole (200mg, 400mg)

- 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, DYNIDAZOL TABLET can cause side effects, although not everybody gets them.

The following side effects have been reported:

Unpleasant taste in the mouth, flurried tongue, nausea, vomiting, gastrointestinal disturbance, hives and swelling, drowsiness, dizziness, headache, loss of control of bodily movements, skin rashes, itchiness, darkening of the urine (due to Metronidazole metabolite).

During intensive and/or prolonged Metronidazole therapy, a few instances of nerve damage or seizures have been reported and moderate decrease in the number of white blood cells.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of DYNIDAZOL TABLET

- Storage

Keep out of reach of children.
Store in a dry place below 30°C.
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

- What it looks like

DYNIDAZOL TABLET 200MG

White in colour, round and biconvex; uncoated tablet.

DYNIDAZOL TABLET 400MG

White in colour, round, flat and scored; uncoated tablet.

- Ingredients

- Active ingredient Metronidazole
- Inactive ingredients
- Corn Starch, Lactose Powder 200 Mesh, Sodium Starch Glycolate, Microcrystalline Cellulose, PVP K90, Magnesium Stearate, Aerosil 200, Croscarmellose Sodium, Chloroform Spirit.

MAL number(s):

DYNIDAZOL TABLET 200MG
MAL19987009AZ

DYNIDAZOL TABLET 400MG
MAL19973017AZ

Manufacturer & Product Registration Holder

Dynapharm (M) Sdn. Bhd.
2497, Mk 1, Lorong Perusahaan Baru 5,
Kawasan Perusahaan Perai 3,
13600 Perai, Pulau Pinang,
Malaysia.

Date of revision

26/10/2018

Serial Number:

NPRA(R4/1)261018/00311