FROTIN FILM COATED TABLET

Metronidazole (200mg)

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What Frotin Tablet is used for

Frotin Tablet is used to treat infections such as sexually transmitted disease caused by parasite, intestinal infection and dental infection.

It is also used as prevention and treatment for certain types of bacterial infection.

How Frotin Tablet works

Frotin Tablet is an antimicrobial medicine. This medicine works by killing the bacteria and other organisms causing these infections.

Before you use Frotin Tablet

- When you must not use it

Do not take this medicine if:

- you are allergic to metronidazole, of similar type antibiotics (nitromidazoles), or anv other ingredients of this medicine (listed in Product Description)
- Before you start to use it

Cases of severe liver toxicity/ acute liver failure in people with Cockayne syndrome have been reported with products containing metronidazole.

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

Inform your doctor if your condition does not improve after a few days treatment.

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

- Cockayne syndrome (rare disorder where affected individual would have slowed growth resulting in short stature, delayed development and abnormally small head size).
- Liver disease
- Blood disorder
- Disease of the brain, spinal cord or

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine

- <u>Taking other medicines</u>

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

Tell your doctor if you are taking any of the following medicines:

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital for epilepsy

If you are not sure, talk to your doctor or pharmacist before taking Frotin Tablet.

How to use Frotin Tablet

- How much to use

Swallow the tablet whole (not chewed) with plenty of water.

Trichomoniasis (parasite that causes infection)

Adults: 2 tablets twice daily for 7 days, or 4 tablets in the morning and 6 tablets in the evening for 2 days or 10 tablets in a single dose.

Amoebiasis infection (infection of the intestine caused by amoeba)

Adults and children more than 10 years old: 2 to 4 tablets three times daily.

Children 7-10 yr: 1-2 tablets 3 times

Children 3-7 yr: 1/2-1 tablet 4 times

Children 1-3 yr: 1/2-1 tablet 3 times daily.

Inflammation of the gum

Adults and children more than 10 years old: 1 tablet 3 times daily.

Children 3-10 yr: ½ tablet 3 times daily.

Bacterial infections

Adults: Initial dose of 4 tablets followed by 2 tablets three times daily.

Children: 7.5 mg/kg 3 times daily.

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

- When to use it

Frotin Tablet should be taken during or after a meal.

- How long to use it

Frotin Tablet need to be taken for 3-10 days depending on the type of infections. Use Frotin Tablet for the duration that your doctor recommends.

Regular clinical and laboratory monitoring are advised by doctor if duration of metronidazole therapy is prescribed for more than 10 days.

- 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.

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- 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 nausea, vomiting, seizure and loss of control of bodily movements.

While you are using Frotin Tablet

- Things you must do

Complete the whole course of antibiotics eventhough you are recovering.

Tell all the doctors, dentists and pharmacists treating you that you are using Frotin Tablet.

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

Take Frotin Tablet only with a doctor's prescription.

- Things you must not do

Do not drink any alcohol while you are using Frotin Tablet and for 24 hours after finishing your course. Drinking alcohol while using Frotin might cause unpleasant side effects, such as nausea, vomiting, stomach pain, hot flushes, palpitations and headache.

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

Do not give Frotin Tablet to anyone else, even if they have the same condition as you.

Do not use any new medicines without consulting your doctor or pharmacist.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel drowsy, dizzy, confuse, hallucinate, convulsions or transient visual disturbance, do not drive or use machines and contact your doctor immediately.

Side effects

Gastrointestinal system: eating disorder, nausea, vomiting and epigastric pain.

Mouth: A sharp, unpleasant metallic taste. furry tongue, inflammation of the tongue, mouth and lips may occur.

Blood profile: Low white blood cell count (leukopenia).

Central Nervous System: Seizure, damage of nerves in hand and feet, dizziness, lack of muscle coordination, confusion, irritability, depression, weakness and difficulty sleeping may occasionally occur.

Allergic reaction: Hives, rash, flushing, nasal congestion, dryness of the mouth and fever.

Other: Yeast infection in vagina, difficult or painful sexual intercourse, decrease in sex drive, inflammation of the rectum and joint pains may occur rarely.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Frotin Tablet

- Storage

Store below 30°C, protect from light & moisture. Keep out of the reach and sight of children.

- 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

A white colour round, film coated tablet, one side impressed with "YSP"

- Ingredients

- Active ingredient(s)Metronidazole
- Inactive ingredients
 Lactose monohydrate
 Sodium Starch Glycolate
 Magnesium Stearate
 Povidone
 Hydroxypropyl Methyl Cellulose
 Magnesium Aluminium Silicate
 Polyethylene Glycol
 Dimethicone
 Titanium Dioxide
- <u>MAL number:</u> MAL20021367AZ

Manufacturer and Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd. Lot 3,5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

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