CLARIMYCIN FILM COATED TABLET

Clarithromycin (250mg, 500mg)

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What CLARIMYCIN FILM COATED TABLET is used for

CLARIMYCIN FILM COATED TABLET is used to treat certain bacterial infections, including the following:

- -Infection of nosepharyns tract (tonsillitis, pharyngitis), and of paranasal sinuses.
- Infection of lower respiratory tract such as bronchitis, bacterial pneumonia and atypical pneumonia.
- Treatment of skin infections such as impetigo, erysipelas, folliculitis, furunculosis and septic wounds.

How CLARIMYCIN FILM COATED TABLET works

CLARIMYCIN FILM COATED TABLET is an antibiotic that belongs to the group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria which cause infections.

Before vou use CLARIMYCIN FILM COATED TABLET

-When you must not use it

Do not take CLARIMYCIN FILM COATED TABLET if:

- you have ever had an allergic reaction to medicines containing clarithromycin and other antibiotics from the macrolide family. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- you have heart diseases or irregular heartbeat
- you have electrolyte disturbances
- you are taking medicine such as terfenadine, which is commonly used to treat allergy reaction.

-Before you start to use it Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had kidney or liver disease.

Pregnancy and lactation

Please consult your doctor before start to use CLARIMYCIN FILM COATED 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 Product CLARIMYCIN FILM COATED TABLET against the benefits they expect it will have for you.

-Taking other medicines

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

Some medicines may affect the way CLARIMYCIN **FILM COATED** TABLET works. These include the following medicines:

- theophylline, medicine for asthma -carbamazepine, medicine for seizure
- digoxin, medicine for heart disease
- warfarin, medicine for blood thinning
- -terfenadine, medicine for allergy reaction

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use CLARIMYCIN FILM COATED TABLET

-How much to use

In adults: One 250mg tab every 12 hours. In cases of severe infections, dosage can be increased up to 500mg every 12 hours.

Your doctor might prescribe a lower dose for you if you have kidney disease.

-When to use it

CLARIMYCIN FILM **COATED** TABLET should be taken according to the time advised by your doctor or pharmacist.

-How long to use it Continue taking CLARIMYCIN FILM COATED TABLET for as long as your doctor recommends. According to severity of infection, up to 6 to 14 days.

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

If you miss a dose of, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

-If you use too much (overdose)

Contact your doctor immediately or go to 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.

While you are using it

-Things you must do

Follow your doctor's instruction when you are taking CLARIMYCIN FILM COATED TABLET.

If you get severe diarrhoea, tell your doctor or pharmacist immediately.

Tell your doctor if you become pregnant while taking CLARIMYCIN FILM COATED TABLET.

-Things you must not do

Do not stop taking this medicine or change the dosing regimen without instruction from your doctor. Do not give CLARIMYCIN FILM COATED TABLET to anyone else, even if they have the same condition as you.

-Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how CLARIMYCIN FILM COATED TABLET affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CLARIMYCIN FILM COATED TABLET.

CLARIMYCIN FILM COATED TABLET treat infections in most people, but it may have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects, such as diarrhea, vomiting, abdominal pain, nausea, headache, altered taste, allergic reaction such urticarial (itching) and mild skin eruptions to anaphylaxis (severe allergic reactions), anxiety, dizziness, insomnia, hallucination, and confusion.

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 \rightarrow Reporting)

Storage and Disposal of CLARIMYCIN FILM COATED TABLET

-Storage

Store at temperature below 30°C. Protect from light and moisture

-Disposal

CLARIMYCIN FILM COATED TABLET should be disposed when your doctor or pharmacist tells you to stop taking this tablet or it has passed the expiry date. Ask your pharmacist how to dispose medicines that are no longer required.

Product description

-What it looks like

CLARIMYCIN FILM COATED TABLET 250MG:

A bright yellow rounded rectangular tablet, one side impressed with "YSP 25".

CLARIMYCIN FILM COATED TABLET 500MG:

A light yellow rounded rectangular tablet, one side impressed with "YSP 50".

-Ingredients

-Active ingredient Clarithromycin

-Inactive ingredients

CLARIMYCIN FILM COATED TABLET

250MG: Povidone

Croscarmellose Sodium Polyethylene Glycol Ouinolone Yellow

Cellulose

Dimethylpolysiloxane

Talc

Cellulose Sodium

Starch

Hydroxypropyl Methylcellulose

Isopropyl Alcohol

Stearic Acid

Sodium Starch Glycolate

Magnesium Stearate

Titanium Dioxide

Aerosil

Sorbic Acid

Sorbitan Trioleate

Purified Water

CLARIMYCIN FILM COATED

TABLET 500MG:

Cellulose

Isopropyl Alcohol

Stearic Acid

Croscarmellose Sodium

Sodium Starch Glycolate

Purified Water

Povidone

Talc

Cellulose Sodium

Starch

Polyethylene Glycol

Magnesium Stearate

Opadryl II Yellow

Aerosil

Sorbic Acid

Sorbitan Trioleate

-MAL number

CLARIMYCIN FILM COATED

TABLET 250MG:

MAL07124607AZ

CLARIMYCIN FILM COATED

TABLET 500MG:

MAL07124609AZ

Manufacturer

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.

Product Registration Holder

Y.S.P Industries (M) Sdn. Bhd.

Lot 3,5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru

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Bangi,

43000 Kajang, Selangor Darul

Ehsan,

Malaysia.

Date of revision

25/02/2016

Serial Number

BPFK(R4/1)160216/00039