

PACKAGE LEAFLET: INFORMATION FOR THE USER

By-Mycin 50mg, 100mg Capsules Doxycycline (as hyclate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What By-Mycin Capsules are and what they are used for
2. What you need to know before you take By-Mycin Capsules
3. How to take By-Mycin Capsules
4. Possible side effects
5. How to store By-Mycin Capsules
6. Contents of the pack and other information

1. WHAT BY-MYCIN IS AND WHAT IS IT USED FOR

The name of your medicine is By-Mycin and the active substance is doxycycline present as doxycycline hyclate. It is available in two strengths: 50mg and 100mg capsules.

By-Mycin Capsules is a tetracycline antibiotic which may be used to treat infections due to gram positive and gram negative bacteria sensitive to this medicine.

It is used to treat many different types of infections including:

- Chest, lung or nasal infections e.g. bronchitis, pneumonia, sinusitis.
- Urinary tract infections (the passage through which urine passes) e.g. cystitis, urethritis.
- Eye infections.
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia.
- Fevers associated with louse or tick bites.
- Malaria, when chloroquine is not effective.
- Acne - 50mg strength only

By-Mycin is also used to prevent certain infections developing; these are scrub typhus (a disease carried by small insects), travellers' diarrhoea, malaria, cholera and leptospirosis (a bacterial infection from contaminated water).

Your doctor may want you to take By-Mycin to treat another infection not listed above. You may also be prescribed an additional medicine to take with By-Mycin to treat your infection. Talk to your doctor if you have any questions, if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BY-MYCIN CAPSULES

Do not take By-Mycin Capsules;

- If you are allergic (hypersensitive) to doxycycline or any tetracyclines or any of the ingredients (listed in section 6) of By-Mycin Capsules.
- If you are pregnant, may become pregnant or are breast-feeding.
- If you suffer from a condition where you have difficulty in swallowing food.

Use of tetracycline antibiotics during tooth development (pregnancy, infancy and in children up to 8 years) may cause permanent tooth discolouration.

There may be circumstances (e.g., severe or life-threatening conditions), where your physician may decide that the benefits outweigh this risk in children below 8 years and doxycycline should be prescribed.

Warnings and precautions:

You should tell your doctor before you take By-Mycin Capsules if any of the following apply to you:

- You are likely to be exposed to strong sunlight or UV light (e.g. sun-bed). You should avoid exposure to strong sunlight while taking this medicine as your skin may be more sensitive to sun burn than normal.
- You have kidney or liver problems.
- You are suspected of having syphilis; your doctor will continue to monitor you after your treatment has stopped.
- You have diarrhoea or usually get diarrhoea when you take antibiotics or have suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using By-Mycin **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.
- You suffer from reflux. By-Mycin may make your condition worse and may not be a suitable medicine for you.
- You suffer from porphyria (a rare disease of blood pigments).
- You have myasthenia gravis (a disease which commonly affects the muscles that control the eyes and eyelids, facial expressions, chewing, swallowing and speaking, but can affect the whole body).
- You suffer from problems with your pancreas.
- You experience increased pressure in your skull (severe headache) with a change in your vision.
- You have difficulties when swallowing or feel discomfort in your throat or stomach after taking By-Mycin tell your doctor immediately. Your doctor may advise you to stop taking By-Mycin.
- You have (or have ever had) systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes and fever). This condition may be worsened by taking By-Mycin.

When used for a long duration, By-Mycin may cause infections that cannot be treated with this antibiotic. Your doctor can explain the signs and symptoms of such types of infections.

Other medicines and By-Mycin Capsules:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

By-Mycin can affect the action of some other medicines, these include:

- Reduced effectiveness of penicillin antibiotics (used to treat infections).
- Increased action of warfarin or coumarins (used to prevent blood clots).
- Reduced effectiveness of antacids (indigestion remedies) and calcium or iron preparation, as they may affect absorption of By-Mycin from your stomach.
- Reduced effectiveness of By-Mycin by barbiturates (sedatives) and medicines used in epilepsy, such as phenytoin or carbamazepine.
- Use of tetracycline antibiotics such as doxycycline and methoxyflurane an anaesthetic has been reported to result in fatal kidney toxicity.
- By-Mycin may reduce the effectiveness of contraceptives (birth control pills).
- Medicines that you have bought for yourself without prescription.

Other warnings**Operation or Dental Surgery:**

If you are undergoing a general anaesthetic for the purposes of an operation or dental surgery you must tell your anaesthetist or dentist that you are taking By-Mycin as you may have more side-effects.

Laboratory Tests

By-Mycin may interfere with some tests; tell your doctor if you need to give samples for laboratory assessment.

By-Mycin Capsules with food, drink and alcohol:

Studies indicate that the absorption of By-Mycin is not affected when taken with food or drink. If By-Mycin upsets your stomach then taking it with food or milk is recommended. Alcohol may reduce the effect of By-Mycin Capsules and should be avoided.

Pregnancy, breast-feeding and fertility:

By-Mycin Capsules must not be used if you are pregnant, may become pregnant or you are breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

By-Mycin is not known to affect your ability to drive and use machines.

However, patients on By-Mycin should not drive or operate machinery unless By-Mycin has been shown not to affect their physical ability.

By-Mycin Capsules contains sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE BY-MYCIN CAPSULES

Always take By-Mycin Capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses for different infections are listed below.

General dosage Information:

Adults and children aged 12 years to less than 18 years: 200mg on the first day then 100mg daily. The length of treatment is dependent on the infection being treated and will be specified by your doctor and on the label of your medicine. Please follow these instructions fully.

Acne: 50mg daily for a minimum of 6 weeks.

Sexually transmitted infections e.g. gonorrhoea, Chlamydia: 100mg twice a day for 7-10 days.

Syphilis: 100mg twice daily for two weeks.

Treatment of Malaria: 200mg daily for at least 7 days (in conjunction with another treatment for malaria e.g. quinine).

Prevention of Malaria: 100mg daily in adults. Take By-Mycin Capsules 1-2 days before travelling to the infected area, continuously during travelling and for 4 weeks after leaving the infected area.

Treatment and prevention of Cholera: 300mg as a single dose for adults.

Prevention of travellers' Diarrhoea: For adults, 200mg on the first day of travel followed by 100mg daily throughout the stay in the area. **If you intend taking By-Mycin for longer than 21 days you should discuss this with your doctor prior to use.**

Stage 1 and 2 Lyme disease: 100mg twice daily for 10-30 days, according to the severity of the disease.

Scrub typhus: 200mg as a single dose, once weekly.

Treatment of infections caused by Leptospira (infections from contaminated water): 100mg twice daily for 7 days.

Prevention of infections caused by Leptospira (infections from contaminated water): 200mg once a week throughout the stay in the infected area and 200mg at the completion of the trip. **If you intend taking By-Mycin for longer than 21 days you should discuss this with your doctor prior to use.**

Fevers caused by lice or ticks: 100mg or 200mg once only.

Infections due to susceptible strains of Bacillus anthracis:

Adults: 100mg twice daily for 60 days.

Children aged 8 years to less than 12 years:

Doxycycline for the treatment of acute infections in children aged 8 years to less than 12 years should be used in situations where other drugs are not available or are not likely to be effective. In such circumstances, the usual doses are:

For children 45 kg or less:

First day: 4.4 mg for each kg of bodyweight (in single or 2 divided doses) then 2.2 mg for each kg of bodyweight (in single or 2 divided doses) from the second day. The length of treatment is dependent on the infection being treated.

In more severe infections, up to 4.4 mg for each kg of bodyweight should be given throughout treatment.

For children, over 45 kg: Dose administered for adults should be used; 200mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

Method of administration

Your capsules should be taken with a full glass of cold fluid in a sitting or standing position in the morning if possible, but if not, at least 1 hour before going to bed.

It is important not to lie down for at least thirty minutes after taking By-Mycin Capsules so that the capsules can move as swiftly as possible to the stomach and prevent irritation of the throat or oesophagus (canal taking food from the mouth to the stomach). If your stomach is upset By-Mycin Capsules can be taken with milk or a meal.

If you take more By-Mycin Capsules than you should:

It is important not to take too many capsules. Contact your nearest hospital casualty department or a doctor for advice if you have swallowed too many capsules or if you think a child has swallowed any. Take this leaflet, and any capsules that you still have, to show the doctor.

If you forget to take By-Mycin Capsules:

If you forget to take a dose at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. If it is almost time to take your next dose, wait until then and then carry on as before.

If you stop taking By-Mycin Capsules:

Keep taking your capsules for as long as your doctor tells you. Do not stop just because you feel better.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can have side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms of an allergic reaction after taking this medicine. Although they are very rare the symptoms can be severe:

- Sudden wheeziness, difficulty breathing, tightness in chest, fever, swelling of eyelids, face or lips, rash or itching (especially the whole body).
- Upset stomach, loss of appetite, persistent bloody diarrhoea (this may occur up to two or three months after the last dose and may be associated with stomach pain or fever). This may occur after treatment with antibiotics and can be a sign of bowel inflammation.
- Headache which, if very severe, may be associated with visual disturbance such as blurred vision or loss of vision. The possible symptoms in benign intracranial hypertension include headache, vomiting, visual disturbances including blurred vision, a localized defect in the visual field bordered by an area of normal vision (scotoma), double vision (diplopia), and possible vision loss, in some cases, even permanent.

If any of the side effects listed below occur, contact your doctor as soon as possible.

- Skin that is more sensitive to sunlight than normal. You may get a skin rash, itching, redness or severe sunburn.
- Inflammation and/or ulcers of the gut.
- Skin rash, flaking or peeling of the skin.

- Severe skin reactions which may cause you to feel unwell.
- Fever, swollen lymph nodes or skin rash. These may be symptoms of a condition known as DRESS (Drug rash with eosinophilia and systemic symptoms) and can be severe and life-threatening.
- Gastrointestinal issues such as burning sensation in the stomach, nausea, vomiting.
- Abdominal pain and Diarrhoea.
- Blood disorders. These are due to changes in numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising or infections.
- Low blood pressure.
- Increased heart rate.
- Aches in the joints or muscles.
- The Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting doxycycline treatment for infections with spirochete such as Lyme disease.

The following side effects may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you:

Common (may affect up to 1 in 100 people):

- Worsening of a disease called systemic lupus erythematosus (SLE). This is an allergic condition which causes joint pain, skin rash and fever.
- Pericarditis (inflammation) affecting the heart.
- Vomiting/Nausea

Uncommon (may affect up to 1 in 1000 people):

- Heartburn
- Vaginal Infection
- Hypotension (low blood pressure)
- Tachycardia (a racing or irregular heartbeat)

Rare (may affect up to 1 in 10,000 people):

- Difficulty in swallowing, sore, painful or inflamed tongue or mouth.
- Anxiety
- Flushing (reddening of the skin).
- Soreness and itching of the rectal and/or genital area.
- Bowel inflammation.
- Decreased appetite, Porphyria, Anorexia
- Stomatitis (inflammation of the mouth and lips)
- Abnormal liver function tests,
- Discolouration of the thyroid tissue when given for long periods. The medicine does not impair thyroid function.
- Bulging fontanelles (soft spot on head) of infants.
- Loosening of the nail from the nail bed after exposure to the sun.
- Increased levels of urea in the blood.
- Inflammation and damage of the liver, yellow skin and eyes (jaundice), inflammation of the pancreas, Hepatic Failure. Ringing or buzzing in your ear.
- Skin Hyperpigmentation (darker patches on skin appearing with chronic use of doxycycline)

Not known (frequency cannot be estimated from the available data):

- discolouration and/or lack of growth of teeth

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BY-MYCIN CAPSULES

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use after expiry date stated on the carton and on the blister. The expiry refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What By-Mycin Capsules contains:

By-Mycin 50mg capsules: The active substance is doxycycline and each capsule contains 50mg as doxycycline hyclate. The other ingredients are sucrose, maize starch, crospovidone, Eudragit (E100), talc. The capsule shells contain gelatine, titanium dioxide (E171), indigocarmine (E132), quinoline yellow (E104).

By-Mycin 100mg capsules: The active substance is doxycycline and each capsule contains 100mg as doxycycline hyclate. The other ingredients are sucrose, maize starch, crospovidone, Eudragit (E100), talc. The capsule shells contain gelatin, titanium dioxide (E171), indigocarmine (E132), erythrosine (E127).

What By-Mycin Capsules looks like and the contents of the pack:

By-Mycin 50mg Capsules have opaque pale green caps and opaque white bodies.

By-Mycin 100mg Capsules have opaque dark blue caps and opaque white bodies.

By-Mycin Capsules are available in packs of:

2 or 28 capsules for 50mg strength.

2 or 28 capsules for 100mg strength.

Not all pack sizes are marketed.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder:

Fannin Ltd.,
South County Business Park,

Manufacturer responsible for batch release:

Toll Manufacturing Services SL.,
C/ Aragoneses 2,

Leopardstown,
Dublin 18.

28108 Alcobendas,
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