

Package leaflet: Information for the patient

Remycin 100 mg film-coated tablets

Doxycycline

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. 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 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 Remycin is and what it is used for
2. What you need to know before you take Remycin
3. How to take Remycin
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1. What Remycin is and what it is used for

Remycin contains the active substance doxycycline.

Remycin is an antibiotic belonging to a group of medicines called tetracyclines. 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.
- other infections such as cholera, brucellosis, leptospirosis and psittacosis.

Remycin is also used to prevent certain infections developing, these are scrub typhus (a disease carried by small insects) travellers' diarrhoea, malaria and leptospirosis (a bacterial infection caused by exposure to bacteria in fresh water contaminated by animal urine).

Your doctor may want you to take Remycin to treat another infection not listed above. You may also be prescribed an additional medicine to take with Remycin to treat your infection. If you have any questions talk to your doctor.

2. What you need to know before you take Remycin

Do not take Remycin if:

- you are allergic (hypersensitive) to doxycycline or any other tetracycline antibiotic or any of the other ingredients listed in section 6.
- you are pregnant or trying to become pregnant.
- you are breast feeding.
- the medicine has been prescribed for a child under the age of 12 years.
- if you suffer from a condition where you have difficulties when swallowing.

You should not use Remycin during periods of tooth development (pregnancy, infancy or in children below 12 years old) as such use may lead to permanent discolouration (yellow-grey-brown) or affect the proper growth of the teeth.

Warnings and precautions

Talk to your doctor or pharmacist before taking Remycin if:

- you are likely to be exposed to strong sunlight or uv light (e.g. on a sun bed). You should avoid exposure to strong sunlight while taking this medicine as your skin may be more sensitive to sunburn than normal.
- you have liver problems or are taking medicines which affect your liver.
- you have severe kidney problems.
- 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 Remycin tell your doctor immediately since it may be necessary to interrupt treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.
- you suffer from acid reflux. Remycin may make your condition worse and may not be a suitable medicine for you.
- you experience increased pressure in your skull (severe headache) with changes in vision.

If you start to have difficulties when swallowing or feel discomfort in your throat or stomach after taking Remycin tell your doctor immediately. Your doctor may advise you to stop taking Remycin.

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

Other medicines and Remycin.

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

Some medicines can reduce the effectiveness of Remycin, these include:

- antacids (indigestion remedies), iron preparations, oral zinc or bismuth. These should not be taken at the same time of day as Remycin.
- carbamazepine, phenytoin (medicines used to control epilepsy) and barbiturates (used to control epilepsy or as a sedative).

Remycin can affect the action of some other medicines, these include:

- increased action of warfarin or coumarins (used to prevent blood clots).

- reduced effectiveness of oral contraceptives (birth control pills).
- reduced effectiveness of penicillin antibiotics (used to treat infections).
- methoxyflurane (a type of anaesthetic).

If you are undergoing general anaesthesia for an operation or dental surgery you must tell your anaesthesiologist or dentist that you are taking doxycycline as you may have more side effects.

Remycin may interfere with some tests, tell your doctor if you need to give samples for laboratory assessment.

Remycin with food, drink and alcohol

Remycin can be taken with or without food.

If Remycin upsets your stomach then taking it with food or milk is recommended.

Alcohol may reduce the effect of Remycin and should be avoided.

Pregnancy and breast feeding

Remycin must not be taken if you are pregnant or 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

This medicine should not affect your ability to drive or use machines.

This product contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially “sodium-free”.

3. How to take Remycin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not take more than your doctor has recommended.

- you must take your tablets as your doctor told you to.
- it is important to swallow each doxycycline tablet whole with a glass of water.
- it is best to take your tablet at the same time(s) each day, when sitting or while standing.
- it is important not to lie down for at least thirty minutes after taking Remycin, so that the tablet can move as swiftly as possible into the stomach and prevent irritation of the throat or oesophagus (canal taking food from the mouth to the stomach).
- if Remycin upsets your stomach, it is recommended to take Remycin with food and drink.
- For the treatment of infections, Remycin can be taken with or without food.
- Alcohol may reduce the effect of Remycin and should be avoided

Dosage

Usual Dose

2 film-coated tablets on the first day, then 1 film-coated tablet daily. For more severe infections 2 film-coated tablets daily should be given for the treatment period. The length of treatment is dependent on the infection being treated.

Sexually Transmitted Diseases

1 film-coated tablet twice daily for 7 - 10 days.

Primary and Secondary Syphilis:

2 film-coated tablets twice daily for at least 14 days. Your doctor will continue to monitor you after your treatment has stopped.

Fevers associated with louse or tick bites

Single dose of one or two film-coated tablets depending on severity.

Treatment of malaria, when chloroquine is non-effective

2 film-coated tablets daily for at least 7 days.

Prevention of malaria:

1 film-coated tablet daily from 1-2 days before travelling to a malarial area until 4 weeks after returning.

Prevention of scrub typhus:

Single dose of 2 film-coated tablets.

Prevention of travellers' diarrhea:

2 film-coated tablets on the first day of travel, followed by 1 film-coated tablet daily throughout the stay in the area. If you are planning to take these tablets for more than 21 days, please consult your doctor.

Treatment of leptospirosis (infections from contaminated water)

1 film-coated tablet twice daily for 7 days.

Prevention of leptospirosis:

2 film-coated tablets once each week during the stay in the area; 2 film-coated tablets on completion of the trip. If you are planning to take these film-coated tablets for more than 21 days, please consult your doctor.

Treatment and prevention of cholera

A single dose of 3 tablets.

Stage 1 and 2 Lyme disease

1 tablet twice daily for 10 to 30 days. The length of treatment depends on how well you respond.

Infections due to susceptible strains of *Bacillus anthracis*

Adults: 1 tablet twice a day for 60 days.

Children under 12 years of age

Remycin film-coated tablets are not recommended for use in children under 12 years of age as it can cause permanent discolouration of tooth enamel and affect bone development.

If you take more Remycin than you should:

If you take too much Remycin contact your doctor or go to the casualty department of the nearest hospital immediately. Always take the labelled medicine package with you, whether there is any Remycin left or not.

If you forget to take Remycin:

If you forget to take a film-coated tablet take it as soon as you can. Take your next film-coated tablet at the right time.

Do not take a double dose to make up for a forgotten film-coated tablets.

If you stop taking Remycin

If you stop taking the tablets too soon, the infection may return. Take the film-coated tablets for the full time of treatment, even when you begin to 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 cause 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 in breathing, chest pain, fever, sudden swellings, rash or itching (especially affecting the whole body).
- upset stomach, loss of appetite, severe, persistent or 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 serious bowel inflammation.

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

- skin rash, or flaking or peeling of the skin.
- severe skin reactions which may cause you to feel very unwell.
- skin that is more sensitive to sunlight than normal. You may get a skin rash, itching, redness or severe sunburn. If this happens stop taking the medicine and tell your doctor.
- 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.
- headache which, if very severe, may be associated with visual disturbance such as blurred vision or loss of vision.
- inflammation and/or ulcers of the gullet.
- 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.
- stomach pain and diarrhoea

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 10 people):

- feeling or being sick.
- 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).

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

- heartburn.

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

- difficulty in swallowing, sore or painful tongue or mouth.
- skin reddening (flushing).
- a ringing or buzzing noise in the ear.
- soreness and itching of the rectal and/or genital area.
- inflammation of the bowel.
- bulging fontanelles (soft spot on head) of infants.
- inflammation and damage to the liver.
- abnormal liver function tests.
- discolouration of the thyroid tissue when given for long periods. The medicine does not impair thyroid function.
- loosening of the nail from the nail bed after exposure to the sun.
- increased levels of urea in the blood.

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

- yellow skin and eyes (jaundice), inflammation of the pancreas discolouration and/or lack of growth of teeth.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side-effects you can help provide more information on the safety of this medicine.

Cyprus

Pharmaceutical Services

Ministry of Health

CY-1475 Nicosia

Fax: +357 22608649

Website: www.moh.gov.cy/phs

5. How to store Remycin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after 'EXP'. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light and moisture.

6. Contents of the pack and other information

What Remycin contains

- The active substance is doxycycline. Each film-coated tablet contains doxycycline hyclate equivalent to 100 mg doxycycline.
- The other excipients are: microcrystalline cellulose, croscarmellose sodium, sodium starch glycolate, magnesium stearate, talc, povidone, hpromellose, macrogol 400, titanium dioxide.

What Remycin looks like and contents of the pack

White, round, film-coated tablets

Pack-sizes:

PVC/Aluminium blisters. Pack-sizes of 10,100 and 1000 film-coated tablets.

PP containers with PE closures. Pack-sizes of 1000 film-coated tablets.

Not all pack-sizes may be marketed.

Marketing authorization Holder and Manufacturer

Remedica Ltd

Aharnon Str., Limassol Industrial Estate,

3056 Limassol, Cyprus

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For internal use: cy-pl-remycin-fc-tabs-a4