

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

ECONOMYCIN 250 mg CAPSULES

Tetracycline Hydrochloride

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 Economyacin is and what it is used for
2. What you need to know before you take Economyacin
3. How to take Economyacin
4. Possible side effects
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1. What Economyacin is and what it is used for

The name of your medicine is Economyacin. It contains the active ingredient tetracycline hydrochloride, which is a broad spectrum antibiotic and is useful in treating a wide range of infections, these include;

- respiratory tract infections such as pneumonia, bronchitis or whooping cough
- urinary tract infections
- sexually transmitted diseases such as chlamydia, gonorrhoea or syphilis
- skin infections such as acne
- infections of the eye such as conjunctivitis
- rickettsial infections such as Q fever or tick fever
- other infections including brucellosis, psittacosis, plague, cholera, leptospirosis, gasgangrene and tetanus.

Economyacin may also be used to prevent infections before or after dental or surgical operations.

If you are not sure why you have been prescribed Economyacin, then please ask your doctor.

2. What you need to know before you take Economyacin

Do not take Economyacin and tell your doctor if you:

- are allergic to tetracycline, other similar antibiotics or any of the other ingredients of this medicine listed in section 6
- have had kidney or liver problems for a long time or severe kidney disease
- have systemic lupus erythematosus (SLE), a condition characterised by a rash (especially on the face), hair loss, fever, malaise and joint pain
- are giving it to a child under 12 years old
- are pregnant or breast-feeding

Warnings and precautions

Take special care with Economyacin and talk to your doctor or pharmacist before taking if you:

- suffer from myasthenia gravis, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- have kidney or liver disease

- are sensitive to sunlight (photosensitivity)

Other medicines and Economycin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those bought without a prescription.

In particular:

- penicillin antibiotics to treat bacterial infections, such as amoxicillin, flucloxacillin or phenoxymethylpenicillin
- vitamin A
- retinoids to treat eczema, acne or other skin conditions, such as tretinoin or adapalene
- medicines to thin the blood and stop blood clots forming, such as warfarin or phenindione
- medicines to increase urine production (diuretics), such as furosemide or spironolactone
- medicines to control diarrhoea, such as kaolin-pectin or bismuth subsalicylate
- medicines to treat diabetes such as insulin, gliclazide or tolbutamide
- medicines which can damage your liver (check with your doctor or pharmacist to see if this applies to any medicines you are taking)
- atovaquone to treat pneumonia
- antacids to treat indigestion or heartburn, or over the counter medicines or supplements containing aluminium, calcium, iron, magnesium, bismuth or zinc. These medicines should not be taken at the same time as Economycin, as the absorption of tetracycline may be reduced
- sucralfate to treat ulcers
- lithium to treat mental health problems
- digoxin to treat an uneven heartbeat or heart failure
- methotrexate used in rheumatoid arthritis
- strontium ranelate used to treat osteoporosis
- colestipol or colestyramine to treat high cholesterol
- ergotamine and methysergide to treat or prevent migraine
- methoxyflurane (an anaesthetic), if you need an operation, tell your doctor or dentist you are taking tetracycline

Economycin may reduce the effect of oral contraceptives (birth control pills). You should use an additional form of contraception while you are taking Economycin.

Economycin with food and drink

Avoid taking this medicine at the same time as food, milk or milk products, as they can affect the body's absorption of tetracycline.

Operations and Tests

If you are having treatment for any other conditions, you must tell the doctor, dentist or nurse that you are taking Economycin.

During long-term treatment blood, kidney and liver tests may be carried out.

Pregnancy and 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 any medicine.

Do not use this medicine during pregnancy or if you are breast-feeding unless your doctor considers it essential, as it may affect the development of your baby.

Driving and using machines

Economycin is not known to affect the ability to drive or operate machinery

Economycin contains tartrazine (E102)

The colourant tartrazine (E102) may cause allergic reactions.

3. How to take Economycin

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

Swallowed the capsules whole with a glass of water, one hour before or two hours after a meal.

Swallow the capsules when standing or sitting down, do not take them immediately before going to bed.

The usual doses are for at least 10 days unless otherwise directed by your doctor:

Dosage:

Your doctor will decide your exact dose, as it depends on your condition.

Adults and children 12 years or over:

General infections:

1 capsule (250 mg) every 6 hours, you may be given 2 capsules (500 mg) initially. For severe infections your doctor may increase your dosage to 500 mg (2 capsules) every 6 hours.

Specific infections:

Skin infections: 1-2 capsules (250-500 mg) daily either as a single dose or in divided doses for three months.

Brucellosis: 2 capsules (500 mg) four times a day with streptomycin.

Sexually transmitted diseases: 2 capsules (500 mg) four times a day for between 7 and 30 days depending on your condition.

Children under 12 years of age:

Economycin is not recommended for use in children under 12 years of age as it can cause permanent discolouration of tooth enamel and affect bone development.

Elderly:

Usual adult dose. Economycin should be used with caution in the treatment of elderly patients.

If you take more Economycin than you should

Contact your doctor or go to the nearest hospital casualty department immediately. Take the package with you so the doctor knows what has been taken.

If you forget to take Economycin

Do not worry, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose

If you stop taking Economycin

You should continue taking Economycin for as long as your doctor has told you to, even if you start to feel better. If you stop before finishing the prescribed course of treatment your infection may still be present or may reappear.

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.

If you get any of the following serious side effects, stop taking Economycin immediately and seek urgent medical advice:

- allergic reaction, the symptoms of which may include skin rash which may be itchy, swelling of your face, eyelids, lips, tongue or throat, sudden wheezing, chest pain or tightness, breathing difficulties, collapse
- increased pressure in the skull, which can cause severe headache, dizziness, 'ringing' in the ears, visual problems including blurred vision, 'blind spots', double vision

- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central blisters. The rash may progress to widespread blistering or peeling of the skin. Additional signs include ulcers in the mouth, throat, nose or genitals, red swollen eyes (conjunctivitis) and flu-like symptoms.
- a decrease in or loss of vision/eyesight
- severe or prolonged diarrhoea which may have blood or mucus in it, this may be a sign of serious bowel inflammation.

Tell your doctor if any of the following side effects occur:

Rare (affects fewer than 1 in 1,000 people)

- inflammation of the liver (hepatitis), liver failure or yellowing of the skin or whites of the eyes (jaundice), changes in liver function (seen in blood tests)
- increased levels of urea, phosphates or acid in the blood or changes in the numbers and types of your blood cells. If you notice increased bruising, bleeding, sore throats, infections, fever, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test
- ulcers in the throat, difficulty swallowing
- problems with your kidneys, causing changes in your urine, tiredness, weakness, shortness of breath and swelling due to fluid retention

Not known: frequency cannot be estimated from the available data

- increased sensitivity to sunlight or artificial sunlight (sun-beds or sun-lamps) causing itching, stinging and burning of the skin. You should limit your exposure to natural sunlight, and avoid exposure to artificial sunlight, where possible.
- overgrowth of some resistant organisms causing infections, such as thrush, affecting the genitals or anus
- pseudomembranous colitis, the symptoms of which include watery diarrhoea, abdominal cramps and fever
- worsening of the inflammatory disease Systemic Lupus Erythematosus (SLE), which causes skin rashes, fever and joint pain
- increase in muscle weakness in patients suffering from myasthenia gravis
- headache
- stomach upsets, feeling or being sick, diarrhoea, loss of appetite, discolouration of tooth enamel, inflammation of the pancreas (pancreatitis) causing discomfort or pain in the abdomen
- poor kidney function leading to changes in the need to or frequency to pass water, swelling in the legs or ankles
- fatty liver, causing tiredness and discomfort in your upper abdomen
- discoloured thyroid tissue (no changes in thyroid function are known to occur)

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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Economycin

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

Store below 25°C in a dry place in well closed containers.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that 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 protect the environment.

6. Contents of the pack and other information

What Economycin Capsules contains

The active substance (the ingredient that makes the capsules work) is tetracycline hydrochloride, each capsule contains 250 mg of the active substance.

The other ingredients are maize starch, sodium starch glycollate, silicon dioxide, magnesium stearate, gelatin, titanium dioxide, tartrazine (E102) and amaranth (E123).

What Economycin Capsules looks like and contents of the pack

Economycin Capsules are opaque yellow and maroon capsules. They are available in pack sizes of 100 and 500 capsules.

Marketing Authorisation Holder

Chelonia Healthcare Limited,
11 Boumpoulinas Street, 3rd Floor, 1060 Nicosia, Cyprus

Manufacturer

Dr. Reddy's Laboratories (UK) Limited,
208-214 York Road, Battersea, London SW11 3SD, United Kingdom.

For any information about this medicine, please contact the Marketing Authorisation Holder.

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