ERYC (erythromycin) - Prescribing Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

ERYC
Erythromycin delayed release capsules USP

Read this carefully before you start taking ERYC and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ERYC.

What is ERYC used for?

ERYC treats certain bacterial infections:
- of the lungs and throat (respiratory tract).
- of skin and other soft tissue, including acne.
- passed during sex (e.g. syphilis and chlamydia).

Antibacterial drugs like ERYC treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, ERYC should be used exactly as directed. Misuse or overuse of ERYC could lead to the growth of bacteria that will not be killed by ERYC (resistance). This means that ERYC may not work for you in the future. Do not share your medicine.

How does ERYC work?

ERYC is an antibiotic. It works by killing or stopping the growth of the bacteria that cause your infection.

What are the ingredients in ERYC?
Medicinal ingredients: Erythromycin
Non-medicinal ingredients: cellulose acetate phthalate, diethyl phthalate, lactose, methanol, methylene chloride, potassium phosphate monobasic and povidone. Gluten-, paraben- and tartrazine-free.
Capsule shell of ERYC 250 mg: FD&C Yellow No. 6, gelatin and titanium dioxide.
Capsule shell of ERYC 333 mg: D&C Yellow No. 10, D&C Red No. 33, gelatin and titanium dioxide.

ERYC comes in the following dosage forms:
Capsules: 250 mg, 333 mg

Do not use ERYC if you:
- are allergic to erythromycin or any other ingredients of ERYC (see What are the ingredients in ERYC?).
are taking any of the following medication:
- dihydroergotamine, ergotamine (for migraine).
- cisapride* (for stomach problems).
- astemizole* and terfenadine* (antihistamines, for treating allergies).
- pimozide (for psychiatric problems).
* no longer marketed in Canada

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ERYC. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- have myasthenia gravis (a disease which causes muscle weakness, difficulty chewing and swallowing and slurred speech).
- have an irregular heartbeat, especially a problem called QT prolongation.
- are pregnant or planning to become pregnant.
- are breastfeeding or planning to breastfeed. Erythromycin is passed to the infant through human breast milk.

Other warnings you should know about:

While taking ERYC
- Follow your doctor’s instructions carefully.
- Tell your doctor and pharmacist that you are taking ERYC if you are about to start taking any new medicines.
- Do not stop taking your medicine until your doctor tells you to, even if you are feeling better.

Do not use ERYC to treat any other medical complaints unless your doctor tells you to.

If you develop diarrhea during or after treatment with ERYC, tell your doctor at once. Do not use any medicine to treat your diarrhea without first checking with your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ERYC:
- alfentanil, midazolam and triazolam (sedatives which may be given before an operation).
- astemizole* and terfenadine* (antihistamines, for treating allergies).
- atorvastatin, lovastatin (for reducing blood cholesterol).
- carbamazepine, hexobarbital, phenytoin (for epilepsy).
- chloramphenicol, clindamycin and lincomycin (for infections).
- cyclosporin (for prevention of rejection after graft or organ transplant).
- cisapride* (for stomach problems).
- digoxin and quinidine (for heart conditions).
• dihydroergotamine, ergotamine (for migraine).
• oral anticoagulants (for preventing blood clots).
• pimozide (for psychiatric problems).
• theophylline (for breathing problems).
* no longer marketed in Canada

How to take ERYC:

Follow your doctor’s instructions carefully about how much ERYC to take and when to take it.

ERYC should be swallowed, at least 30 minutes and preferably 2 hours before or after a meal.

Usual dose:

Adult dose:
• one capsule of 250 mg 4 times a day,
• one capsule of 333 mg three times a day or
• two capsules of 250 mg twice a day.

Your doctor may decide to increase the dose depending on the specific condition you have.

Child dose:
Your child's doctor will decide the dose of ERYC to give to your child, depending on your child's age, weight and on the specific condition your child has.

Overdose:

Do not take more capsules than your doctor has told you to.

If you think you have taken too much ERYC, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you should forget to take your capsule at the usual time, take it as soon as you remember unless it is time to take the next one. Continue with the remaining doses as before. Do not take more than one dose at a time.

What are possible side effects from using ERYC?

These are not all the possible side effects you may feel when taking ERYC. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:
• Nausea.
- Vomiting.
- Stomach pain and discomfort.
- Diarrhea.
- Itching and skin rashes.
- Confusion.
- Hallucinations.
- Vertigo (dizziness, balance problem).
- Seizure.
- Problems with your pancreas.
- Hearing problems.

If they occur, they are likely to be minor and temporary. However, some may be serious and need medical attention.

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk to your healthcare professional</th>
<th>Stop taking drug and get immediate medical help</th>
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</thead>
<tbody>
<tr>
<td><strong>COMMON</strong></td>
<td></td>
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<tr>
<td>Clostridium difficile colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without stomach cramps and fever</td>
<td>Only if severe</td>
<td>In all cases</td>
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<tr>
<td><strong>RARE</strong></td>
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<tr>
<td>Severe allergic reaction: with symptoms such as swollen mouth, throat, lips, difficulty breathing, skin reactions (rash, blisters, hives)</td>
<td>Only if severe</td>
<td>In all cases</td>
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<tr>
<td>Liver problems: nausea, vomiting, abdominal pain and discomfort, yellowing of the skin and eyes</td>
<td>Only if severe</td>
<td>In all cases</td>
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<tr>
<td>Abnormal heart rhythm: Irregularities of the heartbeat (palpitations)</td>
<td>Only if severe</td>
<td>In all cases</td>
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</tbody>
</table>

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.
Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:
- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9
    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store at room temperature 15°C to 30°C. Protect from light.
Keep out of reach and sight of children.

If you want more information about ERYC:
- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer’s website http://www.pfizer.ca, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

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