

PRESCRIBING INFORMATION
Including Patient Medication Information

PrTEVA-AMPICILLIN

Ampicillin Capsules

250 mg and 500 mg ampicillin (as ampicillin trihydrate)

BP

Antibiotic

Teva Canada Limited
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Canada M1B 2K9
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Date of Preparation:
March 26, 2020

Control No: 234940

Pharmacology:

Ampicillin, a semisynthetic penicillin, is similar to benzylpenicillin in its bactericidal action against sensitive organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptide.

Ampicillin differs in vitro spectrum from benzylpenicillin in the gram-negative spectrum. It exerts high in vitro activity against many strains of *H. influenzae*, *N. gonorrhoeae*, *N. meningitidis*, *B. catarrhalis*, *E. coli*, *P. mirabilis*, *B. funduliformis*, *Salmonellae* and *Shigellae*.

In vitro studies have also demonstrated the sensitivity of many strains of the following gram positive bacteria: alpha-and beta-hemolytic streptococci, *S. pneumoniae*, non-beta-lactamase (penicillinase)-producing staphylococci, *B. anthracis*, and most strains of enterococci and clostridia. Ampicillin generally provides less in vitro activity than penicillin G against gram positive bacteria. Because it does not resist destruction by beta-lactamase, it is not effective against beta-lactamase-producing bacteria, particularly resistant staphylococci. All strains of *Pseudomonas* and most strains of *Klebsiella* and *Aerobacter* are resistant. Ampicillin is not active against *Rickettsia*, *Mycoplasma* and 'large viruses' (*Chlamydia*). Ampicillin is acid stable and therefore, well absorbed. Food, however, retards absorption. Ampicillin diffuses readily into most body tissues and fluids; however, penetration into the cerebrospinal fluid and brain occurs only with meningeal inflammation. Ampicillin is excreted largely unchanged in the urine; its excretion can be delayed by concurrent administration of probenecid. In blood serum, ampicillin is the least bound of all the penicillins; an average of about 20% of the drug is bound to the plasma proteins as compared to 60 to 90% for other penicillins.

The administration of a 500 mg dose of ampicillin trihydrate capsules results in an average peak serum concentration of approximately 3.0 ug/mL.

Indications:

The treatment of infections due to susceptible gram-negative organisms (including strains of shigellae, *S. typhosa* and other salmonellae, *E. coli*, *H. influenzae* and *P. mirabilis*) and susceptible gram positive organisms (including streptococci, pneumococci, and non beta lactamase producing staphylococci).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TEVA-AMPICILLIN and other antibacterial drugs, TEVA-AMPICILLIN should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Contraindications:

A history of allergic reaction to penicillin or cephalosporins.

Precautions:

Before therapy, inquiry as to past penicillin or other allergies is essential as reactions occur more frequently in hypersensitive persons. During therapy, if allergic or anaphylactic reactions occur, discontinue treatment and initiate usual measures, i.e., antihistamines, pressor amines or corticosteroids. During long-term therapy, renal, hepatic, and hematopoietic functions should be checked periodically. Candidiasis and other superinfections may occur, especially in debilitated and malnourished patients, or those with low resistance to infection due to corticosteroids, immunosuppressors or irradiation.

The passage of any penicillin from blood into brain is facilitated by inflamed meninges and during

cardiopulmonary bypass. In the presence of such factors and particularly in the presence of renal failure when high serum concentrations can be attained, central nervous system adverse effects including myoclonia, convulsive seizures and depressed consciousness can be expected. Although this complication has not been reported with ampicillin, it should be anticipated.

Safety for use during pregnancy has not been established.

Use in the Elderly: There are no known specific precautions for the use of ampicillin in the elderly.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing TEVA-AMPICILLIN in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions (SCAR) such as acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with beta-lactam treatment. When SCAR is suspected, TEVA-AMPICILLIN should be discontinued and appropriate therapy and/or measures should be taken.

Adverse Effects:

Gastrointestinal: glossitis, stomatitis, black 'hairy' tongue, nausea, vomiting, diarrhea, enterocolitis and pseudomembranous colitis.

Hypersensitivity: Erythematous maculopapular rashes have been reported fairly frequently; urticaria, erythema multi-form, and a few cases of exfoliative dermatitis have been reported. Anaphylaxis is the most serious reaction experienced and has usually been associated with parenteral administration.

Note: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines, and if necessary, systemic corticosteroids. Serious anaphylactic reactions require the immediate use of epinephrine, oxygen and i.v. corticosteroids. In some cases of infectious mononucleosis, where ampicillin has been administered, an extremely high incidence of generalized rash has been reported.

Hematologic: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported. These are usually reversible on discontinuation of the drug, and are believed to be hypersensitivity phenomena.

Dosage Oral:

Oral doses are preferably given 1 hour before meals, and therapy maintained for a minimum of 5 days.

Adults, and children over 20 kg-E.N.T. and respiratory tract infections: 250 mg every 6 hours.

Genitourinary and gastrointestinal tract infections: 500 mg every 6 to 8 hours. For more severe infections, these doses should be increased or doubled. Children under 20 kg-respiratory, genitourinary, and gastrointestinal tract infections:

Body Weight of Child	Total Daily Dosage-Oral
Up to 5 kg (approx. 3 months)	250 to 500 mg

Over 5 kg up to 20 kg	25 to 100 mg/kg
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This total dosage must be divided into equal doses, and each dose administered every 6 hours.

Larger doses may be required for stubborn or severe infections. The children's dosages are intended for individuals whose weights will not result in a calculated dosage greater than that recommended for adults.

In the treatment of chronic urinary tract and intestinal tract infections, frequent bacteriological and clinical appraisal is necessary. Smaller doses than those recommended above should not be used; higher doses may be needed at times. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Continue treatment for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication can be obtained. A minimum of 10 days' treatment is recommended for any infection caused by beta-hemolytic streptococci.

In gonorrhea therapy, perform serologic tests for syphilis initially and monthly for 3 months.

Dosage Forms:

TEVA-AMPICILLIN 250 mg Capsules: Black cap and opaque scarlet body, size #2 hard gelatin capsules. Printed White **NOVO** and **250** on opposing cap and body portions, contains Ampicillin Trihydrate equivalent to 250 mg of Ampicillin. Supplied in bottles of 100 capsules.

TEVA-AMPICILLIN 500 mg Capsules: Black cap and opaque scarlet body, size #0 hard gelatin capsules. Printed White **NOVO** and **500** on opposing cap and body portions, contains Ampicillin Trihydrate equivalent to 500 mg of Ampicillin. Supplied in bottles of 100 capsules.

Non-medicinal ingredients: Magnesium Stearate and Talc.

The capsule shell contains Acid Red 27, D&C Yellow #10, FD&C Red #3, FD&C Yellow #6, Titanium Dioxide, FD&C Blue #1 and Gelatin.

REFERENCE:

1. Prescribing Information for APO-AMPI (ampicillin trihydrate). Apotex Inc., Toronto, Ontario, Canada (Control No.: 217173; Date of Revision: March 20, 2019).

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

TEVA-AMPICILLIN

Ampicillin Capsules

BP

Read this carefully before you start taking TEVA-AMPICILLIN 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 TEVA-AMPICILLIN.

What is TEVA-AMPICILLIN used for?

- **TEVA-AMPICILLIN is used to treat infections.**
- Antibacterial drugs like TEVA-AMPICILLIN treat only bacterial infections. They do not treat viral infections such as common cold.

How does TEVA-AMPICILLIN work?

TEVA-AMPICILLIN is an antibiotic. It stops bacteria from growing and kills them.

What are the ingredients in TEVA-AMPICILLIN?

Medicinal ingredient: Ampicillin Trihydrate

Non-medicinal ingredients (capsules): magnesium stearate and talc.

The capsule shell contains Acid Red 27, D&C Yellow #10, FD&C Red #3, FD&C Yellow #6, Titanium Dioxide, FD&C Blue #1 and Gelatin.

TEVA-AMPICILLIN comes in the following dosage forms:

As 250 mg and 500 mg capsules.

Do not use TEVA-AMPICILLIN if you:

- are allergic to penicillin.
- are allergic to a class of antibiotics called cephalosporins.

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

- allergies
- severe illness
- kidney problems
- prolonged use of antibiotics
- are pregnant or thinking of becoming pregnant
- are breast-feeding

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

How to take TEVA-AMPICILLIN:

- Always take this medicine exactly as your doctor or pharmacist has told you.
- It is best to take TEVA-AMPICILLIN 1 hour before you eat a meal.
- Check with your doctor or pharmacist if you are not sure.
- Although you may feel better early in treatment, TEVA-AMPICILLIN should be used exactly as directed.
- Misuse or overuse of TEVA-AMPICILLIN could lead to the growth of bacteria that will not be killed by TEVA-AMPICILLIN (resistance). This means that TEVA-AMPICILLIN may not work for you in the future.
- Do not share your medicine.

Usual dose:

- Your doctor will decide how much TEVA-AMPICILLIN you should take and how long you should take it for.

Overdose:

If you think you have taken too much **TEVA-AMPICILLIN**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose, take it as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and take the next dose at your regular time.
- Do not take two doses of TEVA-AMPICILLIN at the same time.
- If you are not sure what to do, call your doctor or pharmacist.

What are possible side effects from using TEVA-AMPICILLIN?

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

Side effects may include:

- Nausea
- Vomiting
- Diarrhea

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reactions: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue or throat.			✓
Pseudomembranous colitis (inflammation of the intestine): abdominal cramps, pain or tenderness, dehydration, fever, nausea, watery or bloody diarrhea.			✓
Glossitis (inflammation of the tongue): red, sore or swollen tongue.		✓	
Black hairy tongue	✓		
Stomatitis (mouth sores and swelling): burning sensation and pain in the mouth, difficulty eating, swelling or sores in the mouth.	✓		
Skin rash or peeling skin.		✓	
Anemia (decreased red blood cells): dizziness, feeling tired and weak, loss of energy, shortness of breath.		✓	
Thrombocytopenia (decreased platelets in the blood): bleeding, bruising, fatigue, weakness. Leukopenia (decreased white blood cells): aches, feeling tired, fever, flu-like symptoms, infections.		✓	

<p>Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs):</p> <ul style="list-style-type: none"> • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort 			✓
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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 report any suspected side effects associated with the use of health products to Health Canada by:

Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or Calling toll-free at 1-866-234-2345.

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 in a tightly closed container.

If you want more information about TEVA-AMPICILLIN:

- 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Patient Medication Information on the manufacturer’s website <http://www.tevacanada.com>; or by calling 1-800-268-4127 ext. 3; or email druginfo@tevacanada.com.

This leaflet was prepared by Teva Canada Limited

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