Product Monograph

Including Patient Medication Information

PrTETRACYCLINE

Tetracycline Hydrochloride Capsules

For oral use

250 mg of Tetracycline Hydrochloride

USP

Antibiotic

AA PHARMA INC.
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Date of Authorization:
2026-03-17

Control Number: 302142

Recent Major Label Changes

None at time of the most recent authorization	

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

TETRACYCLINE (tetracycline hydrochloride capsules) is indicated for infections caused by the following microorganisms:

- Rickettsiae (Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, tick fevers), *M. pneumoniae* (PPLO, Eaton agent), agents of psittacosis and ornithosis, agents of *L. venereum* and *G. inguinale*, and the spirochetal agent of relapsing fever (*B. recurrentis*).
- The following gram-negative organisms: *H. ducreyi* (chancroid), *P. pestis* and *P. tularensis*, *B. bacilliformis*. Bacteroides, *V. comma* and *K. fetus*, and Brucella organisms (in conjunction with streptomycin).
- The following gram-negative organisms, when bacteriologic testing indicates appropriate susceptibility to the drug: *E. coli*, *A. aerogenes*, Shigella, Mima, Herellea, *H. influenzae* (respiratory infections), and Klebsiella infections (respiratory and urinary).
- The following gram-positive organisms when bacteriologic testing indicates appropriate susceptibility to the drug: anaerobic streptococci, *S. pyogenes* (for upper respiratory infections due to Group A beta-hemolytic streptococci, penicillin is the drug of choice including prophylaxis of rheumatic fever), *S. pneumoniae*, and *S. aureus*.

  The frequency of resistance to tetracyclines in hemolytic streptococci is highest in strains from infections of the ear, wounds and skin. Tetracyclines should not be prescribed for acute throat infections; also, they are not the drugs of choice in any staphylococcal infection.

  When penicillin is contraindicated, tetracyclines are alternative drugs in the treatment of infections due to: *N. gonorrhoeae*, *T. pallidum* and *T. pertenue* (syphilis and yaws), *L. monocytogenes*, Clostridia, *B. anthracis*, Fusobacterium (Vincent's infection), and Actinomyces.
- In acute intestinal amebiasis, the tetracyclines may be a useful adjunct to amebicides. In severe acne, the tetracyclines may be useful adjunctive therapy.
- Tetracyclines are indicated in the treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence.
- Inclusion conjunctivitis may be treated with oral tetracyclines or with a combination of oral and topical agents.
- Because tetracycline tends to accumulate in certain neoplastic cells and to exhibit a brilliant, yellow gold fluorescence when exposed to ultraviolet light, it may be useful in experienced hands for the diagnosis of malignancy.

Many strains of bacteria have been shown to be resistant to the tetracyclines. These include certain strains of streptococci, staphylococci, pneumococci, gonococci, and many other gram negative organisms. Therefore, culture and sensitivity testing are advised to determine the susceptibility of the infecting organisms to tetracyclines.

Chemotherapy should not be initiated until all the necessary bacteriological investigations have been started.

Microorganisms that have become insensitive to one tetracycline invariably exhibit cross resistance to other tetracyclines.

Some cross resistance between the tetracyclines and chloramphenicol for gram-negative organisms but not for gram-positive ones has been reported. Tetracycline resistant organisms are most likely to be acquired from other individuals in a population where tetracyclines have been widely used.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TETRACYCLINE and other antibacterial drugs, TETRACYCLINE 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.

1.1. Pediatrics

Pediatrics (< 12 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of tetracycline hydrochloride capsules in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use. See 2. Contraindications.

1.2. Geriatrics

Geriatrics (≥ 65 years of age): No data are available to Health Canada; Use in the geriatric population may be associated with differences in safety or effectiveness. See 7.1.4. Geriatrics.

2. Contraindications

TETRACYCLINE (tetracycline hydrochloride capsules) is contraindicated in:

- patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6. Dosage Forms, Strengths, Composition, and Packaging.
- patients with severe renal or hepatic disease.
- **Pregnancy and Lactation**

  TETRACYCLINE is not recommended for use in pregnant or breastfeeding women unless the potential benefit to the patient outweighs the risk to the fetus or child.
- **Children**

  TETRACYCLINE is contraindicated in children under 12 years of age for therapy of common infections or for any condition in which a bactericidal effect is essential (bacterial endocarditis).
- Avoid prophylactic administration to surgical cases, if possible.

4. Dosage and Administration

4.2. Recommended Dose and Dosage Adjustment

Adults should receive an average daily dose of 250 mg 4 times a day. Higher dosages, such as 500 mg 4 times a day may be required for severe infections. In general, the pediatric dosage should supply 22 to 44 mg of tetracycline/kg/day, in divided doses, depending on the type and severity of the infection.

4.4. Administration

Antacids, containing aluminum, calcium, or magnesium and iron salts impair absorption and should not be given to patients taking oral tetracyclines. Foods and some dairy products also interfere with

absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals.

4.5. Missed Dose

If a dose is missed, the patient should take it as soon as it is recognized. If it is almost time for the next dose, skip the missed dose and continue with the next scheduled dose. The patient should be instructed not take 2 doses at the same time.

5. Overdose

Treatment

If ingested, gastric lavage when necessary.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Oral	Capsule 250 mg of Tetracycline Hydrochloride	D&C YELLOW #10, D&C Yellow 10 Aluminum Lake, FD&C BLUE #1, FD&C BLUE #2 Indigo Carmine Aluminum Lake, FD&C RED #40, FD&C Yellow#6, gelatin, iron oxide black, propylene glycol, stearic acid, talc and titanium dioxide.

Description

TETRACYCLINE 250 mg: Yellow opaque body, orange opaque cap, hard gelatin capsule. Imprinted 250. Yellow powder fill, contains tetracycline HCl 250 mg. Available in bottles of 100.

7. Warnings and Precautions

General

The use of TETRACYCLINE during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent tooth discoloration (yellow gray brown). This reaction is more common during long-term use of the tetracyclines, but has been observed following short-term courses. Enamel hypoplasia has also been reported.

Tetracycline drugs, therefore, should **not** be used in this age group unless other drugs are not likely to be effective or are contraindicated.

TETRACYCLINE administration may result in overgrowth of non-susceptible organisms.

Superinfections due to staphylococci and other organisms may occur during oral but rarely during parenteral administration.

C. albicans can produce effects at three levels: proliferation in the mouth can cause disturbances ranging from simple soreness to frank and extensive thrush, which may spread to the pharynx and possibly the bronchi; in the bowel, it can be manifested by diarrhea; also, pruritus ani occurs frequently.

Proteus and Pseudomonas species resistant to tetracyclines may become predominant in the bowel and diarrhea is common. Periodic microbiologic examination of materials, such as stool and sputum, during tetracycline therapy may alert one to changes in flora indicating bacteriologic superinfection in time to avert progression to clinical disease.

If superinfections are encountered, tetracyclines should be discontinued and appropriate therapy started. Superinfection of the bowel by staphylococci may be life threatening.

Adhere closely to expiration dates; ingestion of deteriorated tetracyclines has produced kidney damage corresponding clinically to the acute Fanconi syndrome (nausea, vomiting, albuminuria, glycosuria, aminoaciduria, hypophosphatemia, hypokalemia, and acidosis). Such damage is usually reversed slowly after withdrawal of the deteriorated tetracycline, although fatal reactions have been reported.

All infections due to Group A beta-hemolytic streptococci should be treated for at least 10 days.

Genitourinary

Before treating gonorrhea, a darkfield examination should be made from any lesion suggesting concurrent syphilis. Serological tests for syphilis should be made for at least 4 months afterwards.

Immune

Since sensitivity reactions are more likely to occur in persons with a history of allergy, asthma, hay fever, or urticaria, the preparations should be used with caution in such individuals. Cross sensitization among the various tetracyclines is extremely common.

Monitoring and Laboratory Tests

If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity. Under such conditions, lower than usual doses are indicated and, if therapy is prolonged, serum level determinations of the drug may be advisable.

During long-term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies should be performed.

Musculoskeletal

Tetracyclines form a stable calcium complex in any bone forming tissue. A decrease in the fibula growth rate has been observed in prematures given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Renal

The antianabolic action of tetracycline may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis. Consequently, increasing levels of BUN may not accurately reflect changes in renal function; the serum creatinine will provide a more reliable index.

Sensitivity/Resistance

Development of Drug Resistant Bacteria

Prescribing TETRACYCLINE in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Skin

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should be warned to avoid exposure to direct sunlight and/or ultraviolet light while under treatment with tetracycline drugs, and treatment should be discontinued at the first evidence of skin discomfort.

7.1. Special Populations

7.1.1. Pregnancy

TETRACYCLINE is not recommended for use in pregnant women unless the potential benefit to the patient outweighs the risk to the fetus.

7.1.2. Breastfeeding

TETRACYCLINE is not recommended for use in breastfeeding women unless the potential benefit to the patient outweighs the risk to the child.

7.1.3. Pediatrics

Pediatrics (< 12 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of tetracycline hydrochloride capsules in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use. See 2. Contraindications.

7.1.4. Geriatrics

Geriatrics (≥ 65 years of age): No data are available to Health Canada. There are no known specific precautions for the use of TETRACYCLINE in geriatric populations. However, as renal insufficiency is more frequently seen in geriatric patients, when treating geriatric patients, consideration should be given to the adverse effects of TETRACYCLINE on renal function (see section 7. Warnings and Precautions, Renal).

8. Adverse Reactions

8.5. Post-Market Adverse Reactions

Blood and lymphatic system disorders: Anemia, hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, neutropenia and eosinophilia have been reported.

Cardiac disorders: Pericarditis

Endocrine and Metabolism: When given over prolonged periods, tetracyclines have been reported to produce brown black microscopic discolouration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

Gastrointestinal disorders: Dyspepsia, nausea, vomiting, diarrhea, stomatitis, sore throat, glossitis, black hairy tongue, dysphagia, enterocolitis, and inflammatory lesions (with candidal overgrowth) in the anogenital region, including proctitis and pruritus ani. These reactions have been caused by both the

oral and parenteral administration of tetracyclines but are less frequent after parenteral use.

Hepatobiliary disorders: Hepatic cholestasis has been reported rarely, and is usually associated with high dosage levels of tetracycline. Hepatotoxicity, associated with pancreatitis in some cases, has been attributed to the long-term use of doses larger than those recommended in patients with renal insufficiency or to the concomitant administration of other potentially hepatotoxic drugs. This serious reaction has occurred most often in pregnant or postpartum patients with pyelonephritis.

Immune system disorders: Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, exacerbation of serum sickness like reactions, as fever, rash.

Metabolism and nutrition disorders: Anorexia.

Monitoring and Laboratory Tests: Rise in BUN has been reported and is apparently dose-related. See 7. Warnings and Precautions, Renal.

Musculoskeletal and connective tissue disorders: Exacerbation of systemic lupus erythematosus, arthralgia.

Pregnancy, puerperium and perinatal conditions: Bulging fontanels have been reported in young infants following full therapeutic dosage. This sign disappeared rapidly when the drug was discontinued.

Respiratory, thoracic and mediastinal disorders: Dysphonia

Skin and subcutaneous tissue disorders: Maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon. Onycholysis and nail discolouration have been reported rarely.

Photosensitivity has occurred. See 7. Warnings and Precautions, Skin.

9. Drug Interactions

9.3. Drug-Behaviour Interactions

The interaction of TETRACYCLINE with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4. Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 2 – Established or Potential Drug-Drug Interactions

Non-proprietary name of the drug product	Source of evidence	Effect	Clinical comment
Anticoagulants	T	Tetracyclines have been shown to depress plasma prothrombin activity. Interference with vitamin K synthesis by microorganisms in the gut has been reported.	Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.
Hepatotoxic drugs	T		When it is essential to administer any of the tetracyclines i.v., the blood concentration should not be permitted to exceed 15 mcg/mL and, if possible, other potentially hepatotoxic drugs should be avoided. Presumably, large doses may be expected to have comparable toxicity by either the i.m. or oral route if renal or hepatic insufficiency is present.
Methoxyflurane	T	Concurrent use of methoxyflurane and tetracyclines has been reported to impair renal function seriously, leading in some cases to death.	Concurrent use of methoxyflurane and TETRACYCLINE is not recommended unless the benefits outweigh the risks.
Penicillin	T	Bacteriostatic drugs may interfere with the bactericidal action of penicillin.	It is advisable to avoid giving TETRACYCLINE in conjunction with penicillin.
Antacids, containing aluminum, calcium, or magnesium and iron salts	T	Antacids impair tetracycline absorption.	Antacids should not be given to patients taking oral tetracyclines.

Legend: T = Theoretical

9.5. Drug-Food Interactions

Foods and some dairy products interfere with TETRACYCLINE absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

The antianabolic action of tetracycline may cause an increase in blood urea nitrogen (BUN). While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis. Consequently, increasing levels of BUN may not accurately reflect changes in renal function; the serum creatinine will provide a more reliable index.

If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity. Under such conditions, lower than usual doses are indicated and, if therapy is prolonged, serum level determinations of the drug may be advisable.

During long-term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies should be performed (see 7. Warnings and Precautions, Monitoring and Laboratory Tests).

Interactions with other laboratory tests have not been established.

10. Clinical Pharmacology

This information is not available for this drug product.

11. Storage, Stability, and Disposal

Store at room temperature 15°C to 30°C, preserve in tight, light-resistant containers.

Keep out of reach and sight of children.

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

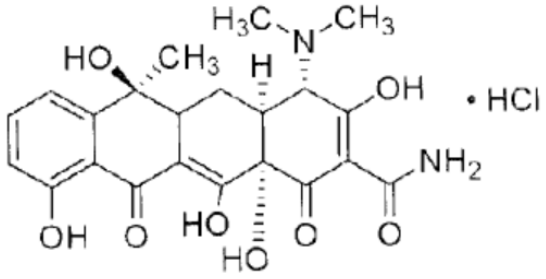
Non-proprietary name of the drug substance: Tetracycline Hydrochloride

Chemical name: (4S,4aS,5aS,6S,12aS)-4-(dimethylamino)-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide hydrochloride.

Molecular formula and molecular mass: $C_{22}H_{24}N_2O_8 \cdot HCl$; 480.9 g/mol

Structural formula:

:



Physicochemical properties: Tetracycline hydrochloride is yellow crystalline powder. Soluble in water, slightly soluble in ethanol (96%), practically insoluble in acetone. It dissolves in solutions of alkali hydroxides and carbonates. Solutions in water become turbid on standing, owing to the precipitation of tetracycline. Its pH range is 1.8 to 2.8

Pharmaceutical standard: USP

14. Clinical Trials

The clinical trial data on which the original indication was authorized is not available.

15. Microbiology

The microbiology data on which the original indication was authorized is not available.

16. Non-Clinical Toxicology

Genotoxicity No studies have been performed to evaluate the genotoxic potential of tetracycline hydrochloride capsules.

Carcinogenicity No long-term animal studies have been performed to evaluate the carcinogenic potential of tetracycline hydrochloride capsules.

Reproductive and developmental toxicology No dedicated animal fertility studies have been performed for tetracycline hydrochloride capsules.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]TETRACYCLINE

Tetracycline Hydrochloride Capsules

This Patient Medication Information is written for the person who will be taking **TETRACYCLINE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **TETRACYCLINE**, talk to a healthcare professional.

What TETRACYCLINE is used for:

- TETRACYCLINE is used to treat infections that are caused by certain types of bacteria.
- Antibacterial drugs like TETRACYCLINE treat only bacterial infections. They do not treat viral infections.

How TETRACYCLINE works:

TETRACYCLINE works to:

- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection in your body.

The ingredients in TETRACYCLINE are:

Medicinal ingredients: Tetracycline Hydrochloride

Non-medicinal ingredients: D&C YELLOW #10, D&C Yellow 10 Aluminum Lake, FD&C Yellow#6, FD&C BLUE #1, FD&C BLUE #2 Indigo Carmine Aluminum Lake, FD&C RED #40, gelatin, iron oxide black, propylene glycol, stearic acid, talc and titanium dioxide.

TETRACYCLINE comes in the following dosage form:

Capsules: 250 mg

Do not use TETRACYCLINE if:

- you are allergic to this drug or to any ingredient in TETRACYCLINE.
- you are allergic to other similar antibiotics (i.e. minocycline or doxycycline).
- you have liver or severe kidney disease.
- you are pregnant or breastfeeding.
- your child is under 12 years old

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

- have kidney disease.

- have allergies, hives, hay fever or asthma.

Other warnings you should know about:

- TETRACYCLINE may increase your sensitivity to sunlight and may cause exaggerated sunburns. Avoid exposure to sunlight or ultraviolet light while taking TETRACYCLINE.
- TETRACYCLINE may cause tooth discolouration (yellow, gray, brown) in children with developing teeth. TETRACYCLINE may also cause other issues with the enamel (the hard protective layer) of your child's teeth.
- Your healthcare professional may request lab tests for you to see how well your kidney and liver are working while taking TETRACYCLINE.

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 TETRACYCLINE:

- Anti-coagulants used to stop the blood clotting (e.g. warfarin).
- Penicillin used to treat bacterial infections.
- Medicines that reduce the amount of stomach acid (containing aluminum, calcium, or magnesium and iron salts). These medicines will reduce the amount of TETRACYCLINE that your body absorbs.
- Medicines used to treat acne such as retinoids.
- Methoxyflurane used to relieve pain.
- Do not take the TETRACYCLINE capsules at the same time as milk or food, as they can make the medicine less effective.
- Tetracycline may reduce the effect of oral contraceptives (birth control pills)

How to take TETRACYCLINE:

- Although you may feel better early in treatment, TETRACYCLINE should be used exactly as directed.
- Misuse or overuse of TETRACYCLINE could lead to the growth of bacteria that will not be killed by TETRACYCLINE (resistance). This means that TETRACYCLINE may not work for you in the future.
- Do not share your medicine.
- Take TETRACYCLINE 1 hour before or 2 hours after meal.

Usual dose:

<u>Adults</u>
1 to 2 capsules 4 times per day.

Overdose:

If you think you, or a person you are caring for, have taken too much TETRACYCLINE, contact a healthcare professional, hospital emergency department, regional poison control center or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget to take TETRACYCLINE capsules, take the dose as soon as you remember and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

Possible side effects from using TETRACYCLINE:

These are not all the possible side effects you may have when taking TETRACYCLINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- Black hairy tongue
- Discoloration of the nails
- Increase sensitivity to sunlight
- Difficulty swallowing
- Hives
- Loss of appetite
- Nausea
- Sore throat
- Stomach pain
- Vomiting

Serious side effects and what to do about them

Symptom/ Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Skin and subcutaneous tissue disorders: Exfoliative dermatitis (severe redness and scaling of skin).			√
Rare			
Skin and subcutaneous tissue disorders: Loosening or separation of a fingernail or toenail, discoloration of the nails.		√	
Unknown			
Blood and lymphatic system disorders: - **Anemia** (decreased number of red blood cells): fatigue, loss of energy,		√	

Symptom/ Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
irregular heartbeats, pale skin, shortness of breath, weakness. - **Hemolytic anemia** (breakdown of red blood cells): pale skin, feeling tired or weak, dizziness, fainting, thirst, rapid breathing. - **Thrombocytopenia** (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, weakness. - **Neutropenia** (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms. - **Eosinophilia** (increased numbers of certain white blood cells): abdominal pain, rash, weight loss, wheezing.			
Cardiac disorders: Pericarditis (sharp pain in chest, cough, swelling in hands, legs, and abdomen, shortness of breath).			√
Gastrointestinal disorders: - inflammation of the mouth, tongue, and esophagus. - **Enterocolitis** (inflammation of the intestines): abdominal pain, diarrhea, loss of appetite, nausea, vomiting, fever, fatigue. - Fungal infection in the area (between the genitals and the anus) causing inflammation and itching.		√	
Gastrointestinal disorders: Indigestion and heartburn, nausea, vomiting, diarrhea, sore throat, difficulty swallowing, pain in the upper abdomen, black hairy tongue, anal itching.	√		
Liver and pancreas disorders: - **Hepatic cholestasis** (decrease in bile flow from the liver): jaundice (yellowing of the skin or whites of eyes), dark urine, light coloured stools.			√

Symptom/ Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
- **Hepatotoxicity** (liver damage): jaundice, abdominal pain, fatigue, loss of appetite, nausea and vomiting.			
Immune system disorders: Itchy, raised red areas on the skin, swelling of the deeper layers of the skin caused by a build-up of fluid, purple or red skin lesions, fever, rash, joint pain, dry skin, severe flaking or peeling of the skin.	√		
Anaphylaxis (allergic reaction): difficulty swallowing or breathing, wheezing; hives or rash; swelling of the face, lips, tongue or throat, rapid swelling under the skin. This can be serious and cause death.			√
Metabolism and nutrition disorders: anorexia (abnormally low body weight, an intense fear of gaining weight and a distorted perception of weight).	√		
Lupus (an autoimmune disease your body's immune system attacks your own tissues and organs): fatigue, fever, joint pain, stiffness and swelling, rash on the face or rashes elsewhere on the body, skin lesions, shortness of breath, chest pain, dry eyes, headaches, confusion and memory loss.		√	
Bulging fontanels: fluid build up in the brain or the brain swells, causing increased pressure inside the skull of young infants.			√
Dysphonia: hoarseness or difficulty making sounds when trying to speak	√		
Skin disorders: - Photosensitivity: increased skin sensitivity to sunlight. - Maculopapular rash and exfoliative dermatitis: small discolored flat macules and raised papules. - Erythematous rash: skin appears	√		

Symptom/ Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
redder than normal.			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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, preserve in tight, light-resistant containers.

Keep out of reach and sight of children.

If you want more information about TETRACYCLINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website (https://www.aapharma.ca/en/); or by calling 1-877-998-9097.

This leaflet was prepared by AA Pharma Inc., 1165 Creditstone Road Unit #1, Vaughan, Ontario, L4K 4N7.

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