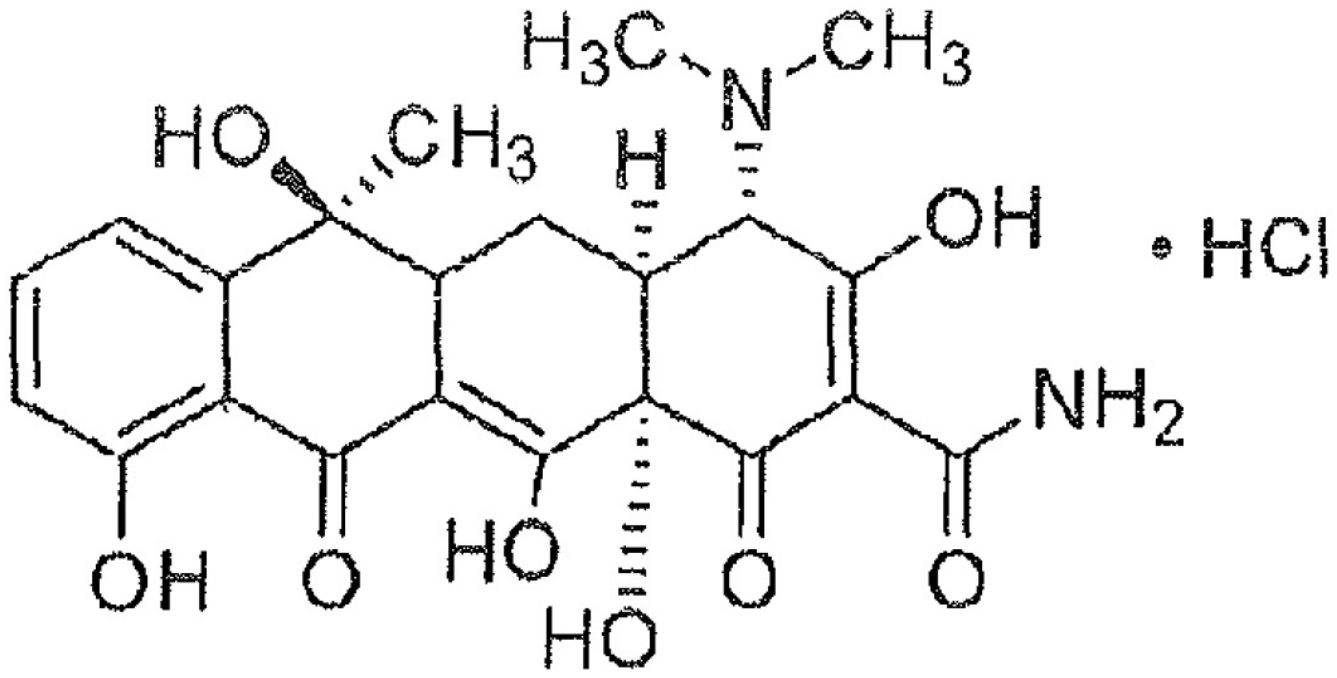
SUMYCIN- tetracycline hydrochloride tablet, film coated
Par Pharmaceutical, Inc.

Tetracycline Hydrochloride Tablets, USP
For Oral Use
Rx only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of tetracycline hydrochloride and other antibacterial drugs, tetracycline hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Tetracycline is a yellow, crystalline powder. Tetracycline is 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. The chemical name for tetracycline hydrochloride is 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12aoctahydro-3,6,10,12,-12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecar-boxamide monohydrochloride. Its structural formula is as follows:



$C_{22}H_{24}N_2O_8.HCl$ M.W.480.9

Each tablet, for oral administration, contains 250 mg or 500 mg tetracycline hydrochloride.

Inactive Ingredients: anhydrous lactose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch and stearic acid. The film coating for the 250 mg and 500 mg are made of D&C RED # 30 / helendon pink aluminium lake, hypromellose and titanium dioxide.

In addition to these, the 250 mg tablet film coating includes triacetin and 500 mg tablet film coating includes polyethylene glycol.

CLINICAL PHARMACOLOGY

Tetracyclines are readily absorbed and are bound to plasma protein in varying degrees. They are concentrated by the liver in the bile and excreted in the urine and feces at high concentrations in a biologically active form.

Microbiology

Tetracyclines are primarily bacteriostatic and exert their antimicrobial effect by the inhibition of protein synthesis by binding to the 30S ribosomal subunit. Tetracycline is active against a broad range of gram-negative and gram-positive organisms. The drugs in the tetracycline class have closely similar antimicrobial spectra, and cross-resistance among them is common.

Tetracycline has been shown to be active against most isolates of the following bacteria, both *in vitro* and in clinical infections as described in the **INDICATIONS AND USAGE** section of the package insert.

Gram-negativeBacteria

Acinetobacter species

Bartonella bacilliformis

Brucella species

Campylobacter fetus

Enterobacter aerogenes

Escherichia coli

Francisella tularensis

Haemophilus ducreyi

Haemophilus influenzae

Klebsiella species

Klebsiella granulomatis

Neisseria gonorrhoeae

Shigella species

Vibrio cholerae

Yersinia pestis

Gram-positive Bacteria

Bacillus anthracis

Streptococcus pyogenes

Streptococcus pneumoniae

Staphylococcus aureus

Listeria monocytogenes

Anaerobes

Bacteroides species
Clostridium species
Fusobacterium fusiforme
Propionibacterium acnes

Other Bacteria

Actinomyces species
Borrelia recurrentis
Chlamydophila psittaci
Chlamydia trachomatis
Rickettsiae
Treponema pallidum
Treponema pallidum subspecies *pertenue*

Parasites

Entamoeba species
Balantidium coli

Susceptibility Test Methods

When available, the clinical microbiology laboratory should provide the results of *in vitro* susceptibility test results for antimicrobial drugs used in resident hospitals to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid the physician in selecting the most effective antimicrobial.

Dilution Techniques

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test method[1,2,4] (broth and/or agar). The MIC values should be interpreted according to the criteria provided in Table 1.

Diffusion Techniques

Quantitative methods that require measurement of zone diameters can also provide reproducible

estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size provides an estimate of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standard test method[1,3,4]. This procedure uses paper disks impregnated with 30 mcg tetracycline to test the susceptibility of bacteria to tetracycline. The disk diffusion interpretive criteria are provided in Table 1.

Anaerobic Techniques

For anaerobic bacteria, the susceptibility to tetracycline can be determined by a standardized test method[5]. The MIC values obtained should be interpreted according to the criteria provided in Table 1.

Table 1: Susceptibility Test Interpretive Criteria for Tetracycline

Bacteria[a]	**Minimal Inhibitory Concentration (mcg/mL)**			**Zone Diameter (mm)**			**Agar Dilution (mcg/mL)**		
	S	**I**	**R**	**S**	**I**	**R**	**S**	**I**	**R**
Acinetobacter spp.	<4	8	>16	>15	12-14	<11	-	-	-
Anaerobes	-	-	-	-	-	-	<4	8	>16
Bacillusanthracis[a]	<1	-	-	-	-	-	-	-	-
Brucella species[a]	<1	-	-	-	-	-	-	-	-
Enterobacteriaceae	<4	8	>16	>15	12-14	<11	-	-	-
Franciscellatularensis[a]	<4	-	-	-	-	-	-	-	-
Haemophilus influenza[e]	<2	4	>8	>29	26-28	<25	-	-	-
Mycoplasma pneumoniae	-	-	-	-	-	-	≤2	-	-
Neisseria gonorrhoeae[b]	-	-	-	>38	31-37	<30	<0.25	0.5-1	>2
Staphylococcus aureus	<4	8	>16	>19	15-18	<14	-	-	-
Streptococcus pneumoniae	<1	2	>4	>28	25-27	<24	-	-	-
Streptococcus pyogenes	<2	4	>8	>23	19-22	<18	-	-	-
Vibrio cholerae	<4	8	>16	>15	12-14	<11	-	-	-
Yersinia pestis	<4	8	>16	-	-	-	-	-	-

[a]The current absence of resistance isolates precludes defining any results other than “Susceptible”. If isolates yielding MIC results other than susceptible, they should be submitted to a reference laboratory for further testing.
[b]Gonococci with 30 mcg tetracycline disk zone diameters of less than 19 mm usually indicate a plasmidmediated tetracycline resistant *Neisseria gonorrhoeae* isolate. Resistance in these strains should be confirmed by a dilution test (MIC greater than or equal to 16 mcg/mL).

A report of *Susceptible* (S) indicates that the antimicrobial is likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations usually achievable at the site of infection. A report of *Intermediate* (I) indicates that the result should be considered equivocal, and, if the bacteria is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone that prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of *Resistant* (R) indicates that the antimicrobial is not likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations usually achievable at the infection site; other therapy should be selected.

Quality Control

Standardized susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of the supplies and reagents used in the assay, and the techniques of the individuals performing the test[1,2,3,4,5,6,7]. Standard tetracycline powders should provide the following range of MIC values noted in Table 2. For the diffusion technique using the 30 mcg tetracycline disk the criteria noted in Table 2 should be achieved.

Table 2: Acceptable Quality Control Ranges for Susceptibility Testing for Tetracycline

QC Strain	Minimal Inhibitory Concentration (mcg/mL)	Zone Diameter (mm)	Agar Dilution (mcg/mL)
Enterococcus faecalis ATCC 29212	8 - 32	-	-
Escherichia coli ATCC 25922	0.5 - 2	18 - 25	-
Haemophilus influenzae ATCC 49247	4 - 32	14 - 22	-
Mycoplasma pneumoniae ATCC 29342	0.06-0.5	-	0.06-0.5
Neisseria gonorrhoeae ATCC 49226	-	30 - 42	0.25 - 1
Staphylococcus aureus ATCC 25923	-	24 - 30	-
Staphylococcus aureus ATCC 29213	0.12 - 1	-	-
Streptococcus pneumoniae ATCC 49619	0.06 - 0.5	27 - 31	-
Bacteroides fragilis ATCC 25285	-	-	0.12 - 0.5
Bacteroides thetaiotaomicron ATCC 29741	-	-	8 - 32

INDICATIONS AND USAGE

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

Tetracycline hydrochloride tablets are indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below:

- Upper respiratory tract infections caused by *Streptococcus pyogenes*, *Streptococcus pneumoniae* and *Hemophilus influenzae*. Note: Tetracycline hydrochloride tablets should not be used for streptococcal disease unless the organism has been demonstrated to be susceptible.
- Lower respiratory tract infections caused by *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Mycoplasma pneumoniae* (Eaton agent, and *Klebsiella sp*.)
- Skin and soft tissue infections caused by *Streptococcus pyogenes*, *Staphylococcus aureaus*. (Tetracyclines are not the drugs of choice in the treatment of any type of staphylococcal infections.)
- Infections caused by rickettsia including Rocky Mountain spotted fever, typhus group infections, Q fever, rickettsialpox.
- Psittacosis caused by *Chlamydophila psittaci*.
- Infections caused by *Chlamydia trachomatis* such as uncomplicated urethral, endocervical or rectal infections, inclusion conjunctivitis, trachoma, and lymphogranuloma venereum.
- Granuloma inquinale caused by *Klebsiella granulomatis*.
- Relapsing fever caused by *Borrelia sp*.
- Bartonellosis caused by *Bartonella bacilliformis*.
- Chancroid caused by *Hemophilus ducreyi*.
- Tularemia caused by *Francisella tularensis*.
- Plaque caused by *Yersinia pestis*.

- Cholera caused by *Vibrio cholerae*.
- Brucellosis caused by *Brucella* species (tetracycline hydrochloride tablets may be used in conjunction with an aminoglycoside).
- Infections due to *Campylobacter fetus*.
- As adjunctive therapy in intestinal amebiasis caused by *Entamoeba histolytica*.
- Urinary tract infections caused by susceptible strains of *Escherichia coli*, *Klebsiella*, etc.
- Other infections caused by susceptible gram-negative organisms such as *E. coli*, *Enterobacter aerogenes*, *Shigella sp.*, *Acinetobacter sp.*, *Klebsiella sp.*, and *Bacteroides sp.*
- In severe acne, adjunctive therapy with tetracycline hydrochloride tablets may be useful.

When penicillin is contraindicated, tetracyclines are alternative drugs in the treatment of the following infections:

- Syphilis and yaws caused by *Treponema pallidum and pertenue*, respectively,
- Vincent's infection caused by *Fusobacterium fusiforme*,
- Infections caused by *Neisseria gonorrhoeae*,
- Anthrax caused by *Bacillus anthracis*,
- Infections due to *Listeria monocytogenes*,
- Actinomycosis caused by *Actinomyces* species,
- Infections due to *Clostridium* species.

CONTRAINDICATIONS

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS

Tooth Development

The use of drugs of the tetracycline-class during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the drugs but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Tetracycline drugs should not be used in this age group, except for anthrax, unless other drugs are not likely to be effective or are contraindicated.

Clostridium difficile Associated Diarrhea

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including tetracyclines, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drugs. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing use of antibacterial drugs not directed against *C. difficile* need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and institute surgical evaluation clinically indicated.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Advise patients apt to be exposed to direct sunlight or ultraviolet lights that this reaction can occur with tetracycline drugs. Discontinue treatment at the first evidence of skin erythema.

Intracranial Hypertension

Intracranial hypertension (IH, pseudotumor cerebri) has been associated with the use of tetracyclines including Achromycin V. Clinical manifestations of IH include headache, blurred vision, diplopia, and vision loss; papilledema can be found on fundoscopy. Women of childbearing age who are overweight or have a history of IH are at greater risk for developing tetracycline associated IH. Concomitant use of isotretinoin and tetracycline should be avoided because isotretinoin, a systemic retinoid, is also known to cause pseudotumor cerebri.

Although IH typically resolve after discontinuation of treatment, the possibility for permanent visual loss exists. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Since intracranial pressure can remain elevated for weeks after drug cessation patients should be monitored until they stabilize.

Skeletal Development

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

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus. Tetracycline drugs should not be used during pregnancy unless absolutely necessary.

Antianabolic Action

The antianabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired renal function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia and acidosis.

Laboratory Monitoring for Long-Term Therapy

In long-term therapy, perform periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies. 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 total doses are indicated, and, if therapy is prolonged, serum level determinations of the drug may be advisable.

PRECAUTIONS

General

As with other antibacterials, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue antibacterial and institute appropriate therapy.

Treat all infections due to Group A beta-hemolytic streptococci for at least ten days.

Perform incision and drainage or other surgical procedures in conjunction with antibacterial therapy, when indicated.

Prescribing tetracycline in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Information for Patients

Counsel patients that antibacterial drugs including tetracycline should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When tetracycline is prescribed to treat a bacterial infection, tell patients that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by tetracycline or other antibacterial drugs in the future.

Laboratory Tests

In sexually transmitted infections, when coexistent syphilis is suspected, perform dark field examinations before treatment is started and the blood serology repeated monthly for at least four months.

Drug Interactions

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline in conjunction with penicillin or other bactericidal antibacterials.

Because the tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.

The concurrent use of tetracycline and methoxyflurane has been reported to result in fatal renal toxicity.

Absorption of tetracyclines is impaired by antacids containing aluminum, calcium or magnesium and preparations containing iron, zinc, or sodium bicarbonate.

Concurrent use of tetracycline may render oral contraceptives less effective.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies are currently being conducted to determine whether tetracycline hydrochloride has carcinogenic potential. Some related antibacterials (oxytetracycline, minocycline) have shown evidence of oncogenic activity in rats.

In two *in vitro* mammalian cell assay systems (L 51784y mouse lymphoma and Chinese hamster lung cells), there was evidence of mutagenicity with tetracycline hydrochloride.

Tetracycline hydrochloride had no effect on fertility when administered in the diet to male and female rats at a daily intake of approximately 400 mg/kg/day, roughly 8 times the highest recommended human dose based on body surface area.

Pregnancy

Teratogenic Effects

Pregnancy Category D

(see **WARNINGS**)

Nonteratogenic Effects

(see **WARNINGS**)

Pregnant women with renal disease may be more prone to develop tetracycline-associated liver failure.

Labor and Delivery

The effect of tetracyclines on labor and delivery is unknown.

Nursing Mothers

Because of potential for serious adverse reaction in nursing infants from tetracyclines, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother (see **WARNINGS**).

Pediatric Use

See **WARNINGS** and **DOSAGE AND ADMINISTRATION.**

ADVERSE REACTIONS

Gastrointestinal: anorexia, nausea, epigastric distress, vomiting, diarrhea, glossitis, black hairy tongue, dysphagia, enterocolitis, and inflammatory lesions (with *Candida* overgrowth) in the anogenital region.

Esophagitis and esophageal ulceration have been reported in patients receiving particularly the capsule and also the tablet forms of tetracyclines.

Most of the patients were reported to have taken medication immediately before going to bed (see **DOSAGE AND ADMINISTRATION**).

Teeth: permanent discoloration of teeth may be caused during tooth development. Enamel hypoplasia has been reported (see **WARNINGS**).

Skin: maculopapular and erythrematous rashes. Exfoliative dermatitis has been reported. Onycholysis and discoloration of the nails have been reported. Photosensitivity is discussed in **WARNINGS**.

Renal Toxicity: an increase in BUN has been reported and is dose related.

Liver: hepatotoxicity and liver failure have been observed in patients receiving tetracycline and in tetracycline-treated patients with renal impairment.

Hypersensitivity Reactions: urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus, and serum sickness-like reactions, as fever, rash, and arthralgia.

Blood: hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, neutropenia and eosinophilia have been reported.

When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Tetracycline is not dialyzable.

DOSAGE AND ADMINISTRATION

Adults: Usual daily dose, 1 gram as 500 mg twice a day or 250 mg four times a day. Higher doses such as 500 mg four times a day may be required for severe infections or for those infections which do not respond to the smaller doses.

For pediatric patients above eight years of age: Usual daily dose, 10 mg/lb to 20 mg/lb (25 mg/kg to 50

mg/kg) body weight divided in four equal doses.

Administration of adequate amounts of fluid with the tablet formulation of tetracycline is recommended to wash down the drug and reduce the risk of esophageal irritation and ulceration (see **ADVERSE REACTIONS**).

Absorption of tetracycline is impaired by antacids containing aluminum, calcium or magnesium and preparations containing iron, zinc or sodium bicarbonate. Food and some dairy products also interfere with absorption.

When used in streptococcal infections, therapy should be continued for 10 days.

For treatment of brucellosis, 500 mg tetracycline hydrochloride tablets four times a day for three weeks accompanied by streptomycin, 1 gram intramuscularly twice daily the first week and once daily the second week.

For the treatment of syphilis in patients allergic to penicillin, the following dosage of tetracycline hydrochloride tablets is recommended: early syphilis (less than one year's duration), 500 mg four times a day for 15 days. Syphilis of more than one year's duration (except neurosyphilis), 500 mg four times a day for 30 days.

For treatment of gonorrhea, the recommended dose is 500 mg by mouth four times a day for seven days.

Uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydiatrachomatis*: 500 mg, by mouth, four times a day for at least seven days.

In cases of moderate to severe acne which, in the judgement of the clinician, require long-term treatment, the recommended initial dosage is 1 gram daily in divided doses. When improvement is noted, reduce dosage gradually to maintenance levels ranging from 125 mg to 500 mg daily. In some patients it may be possible to maintain adequate remission of lesions with alternate day or intermittent therapy. Tetracycline hydrochloride tablets therapy of acne should augment the other standard measures known to be of value. Duration of long-term treatment which can safely be recommended has not been established (see **WARNINGS** and **Carcinogenesis, Mutagenesis, Impairment of Fertility**).

Use in Specific Population

In patients with renal impairment (see **WARNINGS**): decrease total dosage by reduction of recommended individual doses and/or by extending time intervals between doses.

HOW SUPPLIED

Tetracycline Hydrochloride Tablets, USP are available as:

250 mg: Light pink, ovaloid, coated tablet debossed with "732" on one side and plain on the other side.

Available in bottles of:

Bottles of 100 NDC 49884-732-01

Bottles of 1,000 NDC 49884-732-10

500 mg: Pink, ovaloid, coated tablet debossed with "733" on one side and plain on the other side.

Available in bottles of:

Bottles of 100 NDC 49884-733-01

Bottles of 500 NDC 49884-733-05

Dispense in a tight, light-resistant containers as defined in the USP. Use child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

ANIMAL PHARMACOLOGY AND ANIMAL TOXICOLOGY

Hyperpigmentation of the thyroid has been produced by members of the tetracycline class in the following species: in rats by oxytetracycline, doxycycline, minocycline, tetracycline PO_4 and methacycline; in minipigs by doxycycline, minocycline, tetracycline PO_4 and methacycline; in dogs by doxycycline and minocycline; in monkeys by minocycline.

Minocycline, tetracycline PO4, methacycline, doxycycline, tetracycline base, oxytetracycline HCl and tetracycline HCl were goitrogenic in rats fed a low iodine diet. This goitrogenic effect was accomplished by high radioactive iodine uptake. Administration of minocycline also produced a large goiter with high radioiodine uptake in rats fed a relatively high iodine diet.

Treatment of various animal species with this class of drugs has also resulted in the induction of thyroid hyperplasia in the following: in rats and dogs (minocycline), in chickens (chlortetracycline) and in rats and mice (oxytetracycline). Adrenal gland hyperplasia has been observed in goats and rats treated with oxytetracycline.

REFERENCES

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2. Clinical and Laboratory Standards Institute (CLSI). *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard - Tenth Edition*. CLSI document M07-A10 [2015], Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA,
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Rx only

Dist. by:

Par Pharmaceutical

Chestnut Ridge, NY 10977 U.S.A.

Mfg. by:

Par Formulations Private Limited,

9/215, Pudupakkam, Kelambakkam - 603 103.

Made in India

Mfg. Lic. No.: TN00002121

OS732-01-74-01

Issued: 06/2017

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Each film-coated tablet contains:
Tetracycline hydrochloride, USP..... 250 mg

USUAL DOSAGE: See package insert for full prescribing information.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Dispense in tight, light-resistant containers as defined in the USP.
Use child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

NDC 49884-**732**-01

Tetracycline Hydrochloride Tablets, USP

250 mg

Rx only

100 Tablets

PAR PHARMACEUTICAL

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Made in India
Mfg. Lic. No.: TN00002121

N 3 49884 73201 1 LA732-01-74-01 I06/17

Unvarnished Area
W 20 X H 50 mm

Each film-coated tablet contains:
Tetracycline hydrochloride, USP..... 250 mg

USUAL DOSAGE: See package insert for full prescribing information.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Dispense in tight, light-resistant containers as defined in the USP.
Use child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

NDC 49884-**732**-10

Tetracycline Hydrochloride Tablets, USP

250 mg

Rx only

1,000 Tablets

PAR PHARMACEUTICAL

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Made in India
Mfg. Lic. No.: TN00002121

N 3 49884 73210 3 LA732-10-74-01 I06/17

Unvarnished Area

Each film-coated tablet contains:
Tetracycline hydrochloride, USP..... 500 mg

USUAL DOSAGE: See package insert for full prescribing information.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Dispense in tight, light-resistant containers as defined in the USP.
Use child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

NDC 49884-**733**-01

Tetracycline Hydrochloride Tablets, USP

500 mg

Rx only

100 Tablets

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LA733-01-74-01
I06/17

Unvarnished Area
W 20 X H 50 mm

Each film-coated tablet contains:
Tetracycline hydrochloride, USP..... 500 mg

USUAL DOSAGE: See package insert for full prescribing information.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Dispense in tight, light-resistant containers as defined in the USP.
Use child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

NDC 49884-**733**-05

Tetracycline Hydrochloride Tablets, USP

500 mg

Rx only

500 Tablets

PAR PHARMACEUTICAL

Dist. by: **Par Pharmaceutical**
Chestnut Ridge, NY 10977 U.S.A.

Mfg. by: **Par Formulations Private Limited,**
9/215, Pudupakkam, Kelambakkam - 603 103.
Made in India
Mfg. Lic. No.: TN00002121

LA733-05-74-01
I06/17

Unvarnished Area

SUMYCIN

tetracycline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49884-732
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACYCLINE HYDROCHLORIDE (UNII: P6R62377KV) (TETRACYCLINE - UNII:F8VB5M810T)	TETRACYCLINE HYDROCHLORIDE	250 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	PINK (light pink)	**Score**	no score
Shape	OVAL (ovaloid)	**Size**	13mm
Flavor		**Imprint Code**	732
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49884-732-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2017	
2	NDC:49884-732-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA061147	04/04/2017	

SUMYCIN

tetracycline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49884-733
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACYCLINE HYDROCHLORIDE (UNII: P6R62377KV) (TETRACYCLINE - UNII:F8VB5M810T)	TETRACYCLINE HYDROCHLORIDE	500 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	

STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	733
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49884-733-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2017	
2	NDC:49884-733-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA061147	04/04/2017	

Labeler - Par Pharmaceutical, Inc. (092733690)

Revised: 8/2017 Par Pharmaceutical, Inc.