AUSTRALIAN PRODUCT INFORMATION

DOXYLIN®

(doxycycline hyclate) film coated tablet

VIATRIS

1 NAME OF THE MEDICINE

Doxycycline hyclate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each DOXYLIN tablet contains doxycycline hyclate equivalent to either 50 mg or 100 mg of doxycycline.

Excipients with known effect: lactose and trace amounts of sulfites.

For the full list of excipients, see section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

DOXYLIN 50 mg tablet: 7 mm normal convex, yellow film coated tablet, debossed "DE" over "50" on one side, "G" on the reverse.

DOXYLIN 100 mg tablet: 8.5 mm normal convex, yellow film coated tablet, debossed "DE" over "100" on one side, "G" on the reverse.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Note: The 50 mg tablet is not a paediatric formulation.

Doxycycline is indicated in the treatment of infections caused by the following microorganisms:

Mycoplasma pneumoniae: primary atypical pneumonia

Rickettsiae: Queensland tick typhus, epidemic typhus fever, Q fever, murine endemic typhus fever, Australo-Pacific endemic scrub typhus

Chlamydia psittaci: psittacosis

Calymmatobacterium (Donovania) granulomatis: granuloma inguinale

Chlamydia trachomatis: lymphogranuloma venereum, trachoma, inclusion conjunctivitis.

(Doxycycline is 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 doxycycline alone, or in combination with topical agents.)

Doxycycline is indicated in the treatment of infections caused by the following Gram-negative microorganisms:

Vibrio species: cholera

Brucella species: Brucellosis (in conjunction with streptomycin)

Yersinia pestis: plague

Francisella tularensis: tularaemia

Bartonella bacilliformis: Bartonellosis

Bacteroides species.

Doxycycline is indicated, in adults and children older than 10 years, as chemoprophylaxis for malaria caused by *Plasmodium falciparum* and, in combination with other antimalarial agents, against malaria caused by *Plasmodium vivax*. Doxycycline is only able to suppress malaria caused by *P. vivax*. As there are relatively few locations where *P. vivax* does not co-exist to some extent with *P. falciparum*, it is recommended that doxycycline should be used routinely with other agents, e.g. chloroquine.

When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of infections due to:

Treponema pallidum: syphilis

Treponema pertenue: yaws

Neisseria gonorrhoeae: gonorrhoea (see section 4.2 DOSE AND METHOD OF ADMINISTRATION)

Doxycycline may be a useful adjunct to amoebicides in the treatment of acute intestinal amoebiasis.

In the treatment of severe acne, doxycycline may be a useful adjunctive therapy.

Doxycycline is not the drug of choice in the following:

Any type of staphylococcal infection or infections caused by *Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus pyogenes, Enterococcus faecalis*, or any type of enteric bacteria because many strains of these organisms have been shown to be resistant to doxycycline. DOXYLIN should not be used for these infections unless the organism has been shown to be sensitive. For upper respiratory infections due to group A β-haemolytic streptococci, (including prophylaxis of rheumatic fever), penicillin is the usual drug of choice.

4.2 DOSE AND METHOD OF ADMINISTRATION

Note:

1. The 50 mg tablet is not a paediatric formulation.

2. Administration of adequate amounts of fluid with the tablets is recommended to reduce the risk of oesophageal irritation and ulceration. Morning, rather than late night, dosing may be preferable. As the recumbent posture may delay oesophageal transit of the tablets, the patient should not lie down for some time after taking the tablets. To reduce the possibility of gastric irritation, it is recommended that DOXYLIN be given with food or milk. The absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk. Antacids containing aluminium, calcium or magnesium, bismuth salts and preparations containing iron impair absorption and should not be given to patients taking DOXYLIN (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

3. The usual dosage and frequency of administration of DOXYLIN differs from that of other tetracyclines. Exceeding the recommended dosage may result in an increased incidence of side effects. Therapy should be continued for at least 24 to 48 hours after symptoms and fever have subsided.

4. Tetracyclines are not the drugs of choice for the treatment of streptococcal infections (see section 4.1 THERAPEUTIC INDICATIONS). However, when used, therapy should be continued for 10 days.

Adults and Children Over 8 Years (and above 50 kg in weight)

The usual dose is 200 mg on the first day of treatment (100 mg every 12 hours) followed by a maintenance dose of 100 mg/day, which may be administered as a single dose or as 50 mg every 12 hours. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended.

Acute Uncomplicated Gonococcal Infections

100 mg twice daily for 5 to 7 days.

Resistance to tetracyclines is not uncommon amongst gonococci. The use of tetracycline in the treatment of gonorrhoea should, therefore, be accompanied by monitoring of efficacy.

Primary and Secondary Syphilis

300 mg a day in divided doses for at least 10 days.

Louse-borne Typhus

This has been successfully treated with a single oral dose of 100 mg or 200 mg according to severity.

For the prevention of scrub typhus: 200 mg as a single dose.

Severe Acne

Some efficacy has been demonstrated in some individuals at a dose of 50 mg/day over a period of 12 weeks. No data showing efficacy beyond 12 weeks have been submitted.

Malaria chemoprophylaxis

100 mg once daily; commencing two days prior to entering malarious areas, while in the malarious area and for four weeks after leaving the malarious area. A maximum of 100 mg daily for 8 weeks is recommended, as safety after 8 weeks has not been clearly established (see section 4.1 THERAPEUTIC INDICATIONS regards combination with other antimalarial agents for prophylaxis against *P. vivax*).

Children Over 8 Years of Age (and below 50 kg in weight, without skeletal growth retardation)

The adult dose of 100 mg should be recalculated on a weight basis of 2 mg/kg (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Studies to date have indicated that administration of doxycycline at the usual recommended doses does not lead to excessive accumulation of the antibiotic in patients with renal impairment.

4.3 CONTRAINDICATIONS

Hypersensitivity to doxycycline, any of the excipients in DOXYLIN or to any of the tetracyclines.

Use in pregnancy (16 weeks post conception) and use in lactation are contraindicated (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Rare cases of benign intracranial hypertension have been reported after tetracyclines and oral retinoids, such as isotretinoin or etretinate, and vitamin A. Concomitant treatment is therefore contraindicated (see section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)) .

The concurrent use of tetracycline and methoxyflurane has been reported to result in fatal renal toxicity (see section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients taking tetracycline drugs should be advised against exposure to direct sunlight or ultra-violet light, and treatment should be discontinued at the first sign of skin erythema.

Severe Skin Reactions

Severe skin reactions, such as exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving doxycycline. Fixed drug eruptions have occurred with doxycycline and have been associated with worsening severity upon subsequent administrations, including generalized bullous fixed drug eruption (see section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). If severe skin reactions occur, discontinue DOXYLIN immediately and institute appropriate therapy.

Increased Serum Urea

The anti-anabolic action of the tetracyclines may cause an increase in serum urea. Studies to date indicate that this does not occur with the use of doxycycline in patients with impaired renal function.

Intracranial Hypertension

Intracranial hypertension (IH) has been associated with the use of tetracyclines including doxycycline (see section 4.3 CONTRAINDICATIONS and section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). The use of tetracyclines in infants, even in the usual therapeutic doses, may cause increased intracranial pressure and bulging of the fontanelles. Women of childbearing age who are overweight or have a history of IH are at greater risk for developing tetracycline associated IH. Clinical manifestations include headache, blurred vision, diplopia and vision loss. Although intracranial hypertension typically resolves after discontinuation of treatment, the possibility for permanent visual loss exists. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Discontinuation of therapy typically results in prompt return of the pressure to normal. However, since intracranial pressure can remain elevated for weeks after drug cessation patients should be monitored until they stabilise.

Antibiotic associated pseudomembranous colitis

The use of antibiotics may occasionally result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, the antibiotic should be discontinued, and appropriate therapy instituted.

Clostridium difficile associated diarrhoea (CDAD) and antibiotic associated pseudomembranous colitis have been reported with nearly all antibacterial agents including doxycycline and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile* and *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 diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated. Drugs which delay peristalsis, e.g. opiates and diphenoxylate with atropine may prolong and/or worsen the condition and should not be used.

Treatment of Venereal Disease with Coexistent Syphilis

In venereal disease when co-existent syphilis is suspected, proper diagnostic measures including a dark field examination should be performed before treatment is started and the blood serology repeated monthly for at least four months.

Long Term Therapy

In long term therapy, periodic laboratory evaluation of organ systems, including haematopoietic, renal and hepatic studies should be performed.

Oesophagitis/Oesophageal Ulceration

If doxycycline is ingested in an incorrect manner there is a risk of adhesion of the tablet to the oesophagus. If this happens, oesophageal injury may occur. Dysphagia, retrosternal pain, new or worsening heartburn are

possible symptoms of such injury. In order to avoid oesophageal injury, doxycycline must be ingested with at least 100 mL of fluid (half a glass) and the patient must remain upright for at least 30 minutes. Administration in the morning is recommended rather than in the evening.

Rarely, oesophagitis and oesophageal ulceration have been reported in patients receiving doxycycline tablets. Most of these patients took medication immediately before going to bed. Administration of adequate amounts of fluid with the tablets is recommended to reduce the risk of oesophageal irritation and ulceration, and late evening ingestion of the dose should be avoided.

Gastric Irritation

To reduce the possibility of gastric irritation, it is recommended that DOXYLIN be given with food or milk. The absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk.

Treatment of Group A β-haemolytic Streptococci Infections

Tetracyclines are not the medicines of choice for the treatment of streptococcal infections. However, when used, therapy should be continued for 10 days. All infections due to group A β-haemolytic streptococci should be treated for at least 10 days (see section 4.1 THERAPEUTIC INDICATIONS).

Hepatic Effects

Abnormal hepatic function has been reported rarely and has been caused by both the oral and parenteral administration of tetracyclines, including doxycycline.

Use in the Elderly

No data available.

Paediatric Use

Like other tetracyclines, doxycycline forms a stable calcium complex in any bone forming tissue. A decrease in the 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.

The use of tetracyclines, including doxycycline, during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discolouration of the teeth (yellow-grey-brown). This occurs more commonly during long term use of the drugs but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Tetracycline drugs, therefore, should not be used in this age group unless other drugs are unlikely to be effective or are contraindicated.

The use of tetracyclines in infants, even in the usual therapeutic doses, may cause increased intracranial pressure and bulging of the fontanelles. Discontinuation of therapy results in prompt return of the pressure to normal (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE – Intracranial Hypertension).

Effects on Laboratory Tests

False elevations of urinary catecholamine levels may occur due to interference with the fluorescence tests.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Anticoagulants

There have been reports of prolonged prothrombin time in patients taking warfarin and doxycycline. Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage, as tetracyclines have been shown to depress plasma prothrombin activity.

Antacids

Antacids containing aluminium, calcium or magnesium, or other drugs containing these cations, bismuth salts and preparations containing iron impair absorption and should not be given to patients taking DOXYLIN.

Penicillin

It is advisable to avoid giving tetracyclines concomitantly with penicillin as bacteriostatic drugs may interfere with the bactericidal action of penicillin.

Drugs that Reduce Plasma Levels of Doxycycline

Plasma levels of doxycycline are reduced by the ingestion of alcohol or the administration of barbiturates, anticonvulsants (phenytoin, carbamazepine), disodium hydrogen citrate, sodium bicarbonate, sodium lactate, acetazolamide and ethoxzolamide.

Oral Contraceptives

There have been anecdotal reports that concurrent use of tetracyclines may render oral contraceptives less effective and breakthrough bleeding may occur. Unplanned pregnancy may occur with this combination. A barrier method of contraception should be used while taking DOXYLIN and for seven days following completion of the course of DOXYLIN.

Methoxyflurane

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

No data available.

Use in Pregnancy

Pregnancy Category: D

Tetracyclines are safe for use during the first 18 weeks of pregnancy, after which they cause discolouration of the baby's teeth (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE – Paediatric Use).

During the period of mineralisation of a child's teeth (the last half of pregnancy, the neonatal period and the first 8 years of life) tetracyclines may induce hypoplasia of the enamel and discolouration of the teeth. Tetracyclines also accumulate in the growing skeleton. These products should be avoided during the latter half of pregnancy.

Large doses of tetracyclines have caused acute fatty necrosis of the liver in pregnant women, especially those with pyelonephritis.

Use in Lactation

Doxycycline is present in the milk of lactating women. It forms a stable calcium complex in bone-forming tissue and a decrease in the fibula growth has been observed in prematures. The use of medicines of the tetracycline class during tooth development may also cause permanent discolouration of the teeth. Doxycycline should not be given to nursing mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Doxycycline is generally well tolerated.

Cases of benign intracranial hypertension have been reported with tetracyclines. It has also occurred with concomitant vitamin A or retinoids such as isotretinoin and etretinate (see Section 4.3 CONTRAINDICATIONS).

Due to doxycycline's virtually complete absorption, side effects of the lower bowel, particularly diarrhoea, have been infrequent. The following adverse reactions have been observed in patients receiving doxycycline.

More Common Reactions

Dermatological

Photosensitive dermatitis, (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE), erythematous rash, maculopapular rash, morbilliform rash, pustular rash, urticaria, photo-onycholysis and discolouration of the nails.

Gastrointestinal

Nausea, anorexia, vomiting, dysphagia, diarrhoea, oesophagitis, oesophageal ulceration, abdominal pain, glossitis, black hairy tongue.

Hypersensitivity Reactions

Urticaria, exacerbation of systemic lupus erythematosus and Jarisch-Herxheimer reaction has been reported in the setting of spirochete infections treated with doxycycline.

Hepatic

Cholestatic hepatitis, fatty liver degeneration.

Renal

Dose related increase in serum urea (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Musculoskeletal

Tooth discolouration, enamel hypoplasia.

Nervous system disorders

Dizziness

Others

Bulging fontanelles have been reported in young infants following full therapeutic dosage. The sign disappeared rapidly when the drug was discontinued.

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.

Less Common Reactions

Gastrointestinal

Enterocolitis (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE), inflammatory lesions (with monilial overgrowth) in the anogenital region; dyspepsia and pseudomembranous colitis enterocolitis (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE); C. *difficile* diarrhoea;. Abnormal hepatic function has been reported rarely (<1 in 1000), pancreatitis.

Hepatic

Hepatotoxicity, hepatitis.

Skin

Exfoliative dermatitis; Stevens-Johnson syndrome, Toxic Epidermal Necrolysis (TEN), erythema multiforme and fixed drug eruption.

Musculoskeletal

Arthralgia; myalgia.

Genitourinary

Acute renal failure.

Hypersensitivity Reactions

Angioneurotic oedema, anaphylaxis, anaphylactic shock, anaphylactic reaction, anaphylactoid purpura, serum sickness, pericarditis; hypotension, dyspnoea, peripheral oedema, tachycardia,.

Haematological and Reticuloendothelial

Phlebitis associated with intravenous administration, leucopenia, thrombocytopenic purpura, increase in prothrombin time, haemolytic anaemia, eosinophilia.

Nervous System

Flushing, malaise, headache, confusion, taste loss, stupor, hypoaesthesia, paraesthesia, somnolence, benign intracranial hypertension in adults, increased intracranial pressure in infants. In relation to benign intracranial hypertension, symptoms included blurring of vision, scotomata and diplopia. Permanent visual loss has been reported.

Ocular

Conjunctivitis, periorbital oedema.

Hearing/Vestibular

Tinnitus.

Psychiatric

Depression, anxiety, hallucination.

Respiratory

Bronchospasm.

Rare Reactions

Retrosternal pain

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at https://www.tga.gov.au/safety/reporting-problems.

4.9 OVERDOSE

Signs and Symptoms

Tetracyclines, including doxycycline, generally have low toxicity. Severe toxicity following acute overdosage is unlikely, with nausea and vomiting being the most common effects after ingestion of therapeutic and overdose amounts.

Treatment

Treatment may include immediate discontinuation of medication, dilution with water or milk and general supportive care. Antacids may be useful in managing gastric irritation. In most cases, gastrointestinal decontamination is not required. Plasma levels are not clinically useful and specific laboratory monitoring is not needed unless otherwise indicated.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

Microbiology

Doxycycline is primarily bacteriostatic and is active against a wide range of Gram-positive and Gram-negative organisms. It is thought to exert its antimicrobial effect by the inhibition of protein synthesis.

Susceptibility Testing

Dilution or Diffusion Techniques. Either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. CLSI, formerly NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable.

A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism 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, which prevents small-uncontrolled technical factors from causing major discrepancies in interpretation.

A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections.

Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Tetracyclines are readily absorbed, but to a varying extent.

Doxycycline is almost completely absorbed following oral administration. Its absorption is not significantly affected by the presence of food or milk.

Distribution

Tetracyclines are concentrated by the liver in the bile and excreted in the urine and faeces at high concentrations and in a biologically active form.

Metabolism

Following a 200 mg dose to normal adult volunteers, average peak plasma levels of 4.5 microgram/mL of doxycycline occur at approximately 2 hours, decreasing to 1.2 microgram/mL at 24 hours.

The plasma half-life of doxycycline ranges from 10 to 24 hours. No significant difference in serum half-life has been seen in individuals with normal and severely impaired renal function. Haemodialysis does not alter serum half-life.

The metabolism of doxycycline in humans has not been investigated. *In vitro* serum protein binding of doxycycline varies from 23 to 93%.

Excretion

More than 90% of an oral dose of doxycycline is eliminated from the body within 72 hours of drug administration. The fraction of drug that is not eliminated with urine is mainly excreted in the faeces.

Excretion of doxycycline by the kidney is about 40% in 72 hours in individuals with normal renal function (creatinine clearance above 75 mL/min). Excretion may fall to as low as 1 to 5% in 72 hours in individuals with severe renal insufficiency (creatinine clearance below 10 mL/min).

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

DOXYLIN 50 tablets contain colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, Opadry Yellow OY-LS-32814 (ARTG PI No. 2734), pregelatinised maize starch

DOXYLIN 100 tablets contain colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, Opadry Yellow OY-LS-32814 (ARTG PI No. 2734), pregelatinised maize starch

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30ºC.

6.5 NATURE AND CONTENTS OF CONTAINER

Container type: blister pack (PVC/PVDC/Al)

Pack sizes:

50 mg: blister pack: 25 tablets

100 mg: blister packs: 7 and 21 tablets

Some strengths, pack sizes and/or pack types may not be marketed.

Australian Register of Therapeutic Goods (ARTG)

AUST R 63511 - DOXYLIN 50 doxycycline 50 mg (as hyclate) tablet blister pack

AUST R 63509 - DOXYLIN 100 doxycycline 100 mg (as hyclate) tablet blister pack

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.

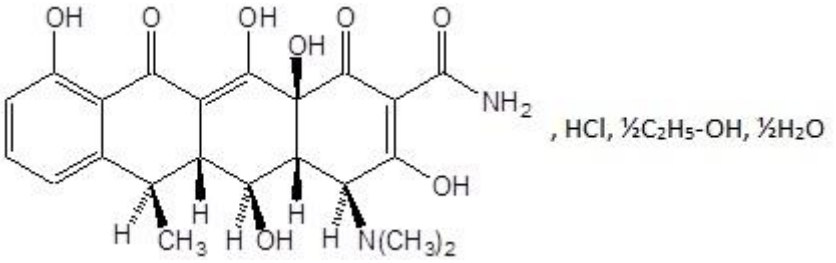
6.7 PHYSICOCHEMICAL PROPERTIES

Chemical Structure

Doxycycline is a yellow, crystalline powder, hygroscopic. It is freely soluble in water and in methanol, sparingly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and carbonates.

Doxycycline is a broad-spectrum antibiotic synthetically derived from oxytetracycline. It has a high lipid solubility and a low affinity for calcium binding, is highly stable in normal human serum, and will not degrade into an epianhydro form.

The chemical structure of doxycycline hyclate is shown below:



Chemical name: hemiethanol hemihydrate of (4S,4aR,5S,5aR,6R,12aS)-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide

Molecular formula: $C_{22}H_{24}N_2O_8$,HCl, ½C_2H_6O,½H_2O

Molecular weight: 512.9

CAS Number

24390-14-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

Alphapharm Pty Ltd trading as VIATRIS

Level 1, 30 The Bond

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Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

9 DATE OF FIRST APPROVAL

22/05/1998

10 DATE OF REVISION

14/10/2025

Summary Table of Changes

Section Changed	Summary of New Information
All	Minor editorial changes
4.4	Addition of "Severe Skin Reactions"
4.8	Addition of "erythema multiforme and fixed drug eruption"

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