PRODUCT MONOGRAPH

PrJAMP Doxycycline
Doxycycline Capsules USP

20 mg Doxycycline (as Doxycycline Hyclate)

COLLAGENASE INHIBITOR FOR PERIODONTAL USE

JAMP Pharma Corporation
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PRODUCT MONOGRAPH

PrJAMP Doxycycline
(Doxycycline Capsules USP)
20 mg Doxycycline (as Doxycycline Hyclate)

THERAPEUTIC CLASSIFICATION

Collagenase Inhibitor for Periodontal Use

ACTIONS AND CLINICAL PHARMACOLOGY

JAMP Doxycycline capsule contains doxycycline hyclate which is a semi-synthetic tetracycline. Doxycycline is an inhibitor of collagenase activity. Studies have shown that doxycycline reduces the elevated collagenase activity in the gingival crevicular fluid of patients with chronic adult periodontitis, in an action unrelated to its antibacterial mode of action. The clinical significance of these findings is not known (for details see CLINICAL TRIALS).

Pharmacokinetics
The pharmacokinetics of doxycycline following oral administration of doxycycline hyclate were investigated in 3 volunteer studies involving 87 adults. Pharmacokinetic parameters following single oral dose and at steady-state in healthy subjects indicated for a single 20 mg dose, a C_{max} of 400 ng/mL and $T_{1/2}$ of 18.4 hours, and for the steady-state 20 mg BID, a C_{max} of 790 ng/mL and the $T_{1/2}$ has not been determined. These blood levels are considered below the antimicrobial activity of doxycycline.

INDICATIONS AND CLINICAL USE

JAMP Doxycycline is indicated for use as an adjunct to scaling and root planing to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis.

JAMP Doxycycline contains an antibacterial ingredient, doxycycline. To reduce the development of drug-resistant bacteria and maintain the effectiveness of doxycycline, JAMP Doxycycline should only be used for the authorized indication and clinical use.

CONTRAINDICATIONS

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines, and in patients with myasthenia gravis. JAMP Doxycycline should not be used during tooth development (second half of pregnancy, infancy and, in childhood).

WARNINGS

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 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 AND IN PREGNANT OR NURSING MOTHERS UNLESS THE POTENTIAL BENEFITS MAY BE ACCEPTABLE DESPITE THE POTENTIAL RISKS.

Doxycycline can cause fetal harm when administered to a pregnant woman. 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 any tetracyclines are used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients apt to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs, and treatment should be discontinued at the first evidence of skin erythema.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Doxycycline hyclate was evaluated in a long-term animal study, no evidence of carcinogenic potential was obtained. Evidence of oncogenic activity was obtained in studies with related compounds, i.e., oxytetracycline (adrenal and pituitary tumors), and minocycline (thyroid tumors).

Doxycycline hyclate demonstrated no potential to cause genetic toxicity in an *in vitro* point mutation study with mammalian cells (CHO/HGPRT forward mutation assay) or in an *in vivo* micronucleus assay conducted in CD-1 mice. However, data from an *in vitro* assay with CHO cells for potential to cause chromosomal aberrations suggests that doxycycline hyclate is a weak clastogen.

Oral administration of doxycycline hyclate to male and female Sprague-Dawley rats adversely affected fertility and reproductive performance, as evidenced by increased time for mating to occur, reduced sperm motility, velocity, and concentration, abnormal sperm morphology, and increased pre- and post-implantation losses. Doxycycline hyclate induced reproductive toxicity at all dosages that were examined in this study, as even the lowest dosage tested (50 mg/kg/day) induced a statistically significant reduction in sperm velocity. Note that 50 mg/kg/day is approximately 10 times the amount of doxycycline hyclate contained in the recommended daily dose of doxycycline hyclate for a 60 kg human when compared on the basis of body surface area estimates (mg/m^2). Although doxycycline impairs the fertility of rats when administered at sufficient dosage, the effect of doxycycline hyclate on human fertility is unknown.

Pregnancy
Teratogenic Effects
Pregnancy Category D. Results from animal studies indicate that doxycycline crosses the placenta and is found in fetal tissues.

Susceptibility/Resistance

Development of Drug Resistant Bacteria
Prescribing JAMP Doxycycline in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth

If superinfection is suspected, JAMP Doxycycline treatment should be discontinued and appropriate measures should be taken.

PRECAUTIONS

Although not seen in clinical trials, overgrowth by opportunistic microorganisms, as with other antimicrobials, may occur. Exceeding the recommended dose of doxycycline hyclate may result in the following:

The use may increase the incidence of vaginal candidiasis.

JAMP Doxycycline should be used with caution in patients with a history or predisposition to oral candidiasis. The safety and effectiveness of doxycycline hyclate have not been established for the treatment of periodontitis in patients with coexistent oral candidiasis.

Laboratory Tests

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

Drug Interactions

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

Since bacterial antibiotics, such as the tetracycline class of antibiotics, may interfere with the bactericidal action of members of the β-lactam (e.g., penicillin) class of antibiotics, it is not advisable to administer these antibiotics concomitantly.

Absorption of doxycycline is impaired by antacids containing aluminum, calcium, or magnesium, and iron-containing preparations. Absorption is also impaired by bismuth subsalicylate.

Barbiturates, carbamazepine, and phenytoin decrease the half-life of doxycycline.

The concurrent use of tetracycline and Penthrane (methoxy-fluorane) has been reported to result in fatal renal toxicity.

Concurrent use of doxycycline may render oral contraceptives less effective.

Drug/Laboratory Test Interactions

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

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials of Doxycycline Hyclate

In clinical trials of adult patients with periodontal disease 213 patients received doxycycline hyclate 20 mg BID over a 9 - 12-month period. The most frequent adverse reactions occurring in studies involving treatment with doxycycline hyclate or placebo are listed below:

Incidence (%) of Adverse Reactions in Doxycycline Hyclate Clinical Trials		
Adverse Reaction Doxycycline Hyclate	20 mg BID (n=213)	Placebo (n=215)
Headache	55 (26%)	56 (26%)
Common Cold	47 (22%)	46 (21%)
Flu Symptoms	24 (11%)	40 (19%)
Tooth Ache	14 (7%)	28 (13%)
Periodontal Abscess	8 (4%)	21 (10%)
Tooth Disorder	13 (6%)	19 (9%)
Nausea	17 (8%)	12 (6%)
Sinusitis	7 (3%)	18 (8%)
Injury	11 (5%)	18 (8%)
Dyspepsia	13 (6%)	5 (2%)
Sore Throat	11 (5%)	13 (6%)
Joint Pain	12 (6%)	8 (4%)
Diarrhea	12 (6%)	8 (4%)
Sinus Congestion	11 (5%)	11 (5%)
Coughing	9 (4%)	11 (5%)
Sinus Headache	8 (4%)	8 (4%)
Rash	8 (4%)	6 (3%)
Back Pain	7 (3%)	8 (4%)
Back Ache	4 (2%)	9 (4%)
Menstrual Cramp	9 (4%)	5 (2%)
Acid Indigestion	8 (4%)	7 (3%)
Pain	8 (4%)	5 (2%)
Infection	4 (2%)	6 (3%)
Gum Pain	1 (0.5%)	6 (3%)
Bronchitis	7 (3%)	5 (2%)
Muscle Pain	2 (1%)	6 (3%)

Note: Percentages are based on total number of study participants in each treatment group.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Dialysis does not alter serum half-life and thus would not be of benefit in treating cases of overdose.

DOSAGE AND ADMINISTRATION

THE DOSAGE OF JAMP DOXYCYCLINE DIFFERS FROM THAT OF DOXYCYCLINE USED TO TREAT INFECTIONS. EXCEEDING THE RECOMMENDED DOSAGE MAY RESULT IN AN INCREASED INCIDENCE OF SIDE EFFECTS INCLUDING THE DEVELOPMENT OF RESISTANT MICROORGANISMS.

JAMP Doxycycline 20 mg twice daily as an adjunct following scaling and root planing may be administered for up to 9 months. Safety beyond 12 months and efficacy beyond 9 months have not been established.

JAMP Doxycycline should be administered at least one hour prior to morning and evening meals.

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

PHARMACEUTICAL INFORMATION

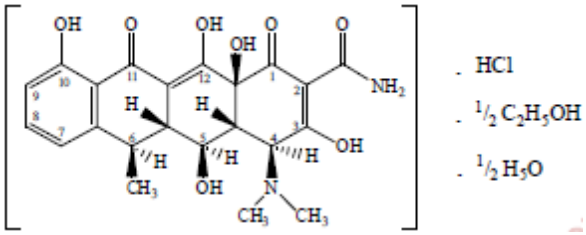
Drug Substance

Proper Name: Doxycycline hyclate

Chemical Name:

(4*S*,4a*R*,5*S*,5a*R*,6*R*,12a*S*)-4-(Dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide hydrochloride hemiethanol hemihydrate.

Structural Formula:



Molecular Formula: $C_{22}H_{24}N_2O_8$, HCl , 1/2 C_2H_5OH , 1/2 H_2O

Molecular Weight: 512.9 g/mol

Description: Doxycycline hyclate is a yellow crystalline powder. It is freely soluble in water and in methanol. Sparingly soluble in ethanol (96 per cent). pH is between 2.0 and 3.0 (solution in water containing 10 mg of doxycycline per mL).

Composition: JAMP Doxycycline contains doxycycline hyclate equivalent to 20 mg of doxycycline. Doxycycline is synthetically derived from oxytetracycline.

Non-medicinal ingredients: Black iron oxide, croscarmellose sodium, gelatin, lactose monohydrate, magnesium stearate, propylene glycol, potassium hydroxide, shellac, stearic acid, and titanium dioxide.

AVAILABILITY AND DOSAGE FORM

JAMP Doxycycline (white opaque cap imprinted with 'JP' in black lettering and white opaque body imprinted with 'DC 20 mg' in black lettering, size "2" hard gelatin capsules) contains doxycycline hyclate equivalent to 20 mg doxycycline. Supplied in bottle of 60 capsules.

Storage
All products are to be stored at controlled room temperatures of 15°C - 30°C and dispensed in tight, light-resistant containers (U.S.P.), protected from excessive humidity.

MICROBIOLOGY

Doxycycline is a member of the tetracycline class of antibiotics. The dosage of doxycycline achieved with this product during administration is well below the concentration required to inhibit microorganisms commonly associated with adult periodontitis. Clinical studies with this product demonstrated no effect on total anaerobic and facultative bacteria in plaque samples from patients administered this dose regimen for 9 to 18 months. This product should not be used for reducing the number of or eliminating those microorganisms associated with periodontitis.

While short-term therapy may not lead to alteration of microflora, the long-term exposure effects have not been studied and cannot be predicted.

CLINICAL PHARMACOLOGY

Pharmacokinetic Parameters for Doxycycline Hyclate					
	n	**C_{max} (ng/mL)**	**T_{max} (hr)**	**Cl/F (L/hr)**	**$t_{1/2}$ (hr)**
Single-dose 20 mg	**42**	**400 ± 142**	**1.5 (0.5 - 4.0)**	**3.80 ± 0.85**	**18.4 ± 5.38**
Steady-State 20 mg BID	**30**	**790 ± 285**	**2 (0.98 - 12.0)**	**3.76 ± 1.06**	**Not Determined**

Absorption
Doxycycline is virtually completely absorbed after oral administration. Following 20 mg doxycycline, twice a day, in healthy volunteers, the mean peak concentration in plasma was 790 ng/mL and the average steady-state concentration was 482 ng/mL. The effect of food on the absorption of doxycycline from doxycycline hyclate capsules has not been studied.

Distribution
Doxycycline is greater than 90% bound to plasma proteins. Its apparent volume of distribution is variously reported as between 52.6 and 134 L.[4,6]

Metabolism
Major metabolites of doxycycline have not been identified. However, enzyme inducers such as barbiturates, carbamazepine, and phenytoin decrease the half-life of doxycycline.

Excretion
Doxycycline is excreted in the urine and feces as an unchanged drug. It is variously reported that between 29% and 55.4% of an administered dose can be accounted for in the urine by 72 hours.[5,6] Half-life averaged 18 hours in subjects receiving a single 20 mg doxycycline dose.

Special Populations

Geriatric
Doxycycline pharmacokinetics have not been evaluated in geriatric patients.

Pediatric
Doxycycline pharmacokinetics have not been evaluated in pediatric patients (see WARNINGS).

Gender
A study was conducted on 42 subjects where doxycycline pharmacokinetics were compared in men and women. It was observed that Cmax was approximately 1.7-fold higher in women than in men. There were no apparent differences in other pharmacokinetic parameters.

Race
Differences in doxycycline pharmacokinetics among racial groups have not been evaluated.

Renal Insufficiency
Studies have shown no significant difference in serum half-life of doxycycline in patients with normal and severely impaired renal function. Hemodialysis does not alter the half-life of doxycycline.

Hepatic Insufficiency
Doxycycline pharmacokinetics have not been evaluated in patients with hepatic insufficiency.

Drug Interactions
See PRECAUTIONS.

Clinical Study

In a randomized, multi-centered, double-blind, 9-month Phase 3 study involving 190 adult patients with periodontal disease [at least two probing sites per quadrant of between 5 and 9 mm pocket depth (PD) and attachment level (ALv)], the effects of oral administration of 20 mg twice a day of doxycycline hyclate plus scaling and root planing (SRP) were compared to placebo control plus SRP. Both treatment groups were administered a course of scaling and root planing in 2 quadrants at Baseline. Measurements of ALv, PD and bleeding-on-probing (BOP) were obtained at Baseline, 3, 6, and 9 months from each site about each tooth in the two quadrants that received SRP using the UNC-15 manual probe. Each tooth site was categorized into one of three strata based on Baseline PD: 0-3 mm (no disease), 4-6 mm (mild/moderate disease), > 7 mm (severe disease). For each stratum and treatment group, the following were calculated at month 3, 6, and 9: mean change in ALv from baseline, mean change in PD from baseline, mean percentage of tooth sites per patient exhibiting attachment loss of > 2 mm from baseline, and percentage of tooth sites with bleeding on probing.

The results are summarized in the following table:

Clinical Results at Nine Months of Doxycycline Hyclate Capsules, 20 mg as an adjunct to SRP			
Parameter	**Baseline Pocket Depth**		
	0-3 mm	**4-6 mm**	**≥ 7 mm**
Number of Patients Doxycycline Hyclate Capsules 20 mg BID	90	90	79
Number of Patients (Placebo)	93	93	78
Mean Gain (SD^{ff}) in ALv^{T} Doxycycline Hyclate Capsules 20 mg BID Placebo	 0.25 (0.29) mm 0.20 (0.29) mm	 1.03 (0.47) mm* 0.86 (0.48) mm	 1.55 (1.16) mm* 1.17 (1.15) mm
Mean Decrease (SD^{ff}) in PD^{T} Doxycycline Hyclate Capsules 20 mg BID Placebo	 0.16 (0.19) mm** 0.05 (0.19) mm	 0.95 (0.47) mm ** 0.69 (0.48) mm	 1.68 (1.07) mm** 1.20 (1.06) mm
% of Sites (SD^{ff}) with loss of $ALv^{T} \geq 2$ mm Doxycycline Hyclate Capsules 20 mg BID Placebo	 1.9 (4.2) % 2.2 (4.1) %	 1.3 (4.5) % 2.4 (4.4) %	 0.3 (9.4) % 3.6 (9.4) %
% of Sites (SD^{ff}) with BOP^{r} Doxycycline Hyclate Capsules 20 mg BID Placebo	 39 (19) %** 46 (19) %	 64 (18) %* 70 (18) %	 75 (29) % 80 (29) %

* $p<0.050$ vs. the placebo control group. ** $p<0.010$ vs. the placebo control group.
ALv^{T}=Clinical Attachment Level PD^{T}=Pocket Depth BOP^{r}=Bleeding on Probing
SD^{ff}=Standard Deviation

Comparative Bioavailability Study

A randomized, two-way, single-dose, crossover comparative bioavailability study of ^{Pr}JAMP Doxycycline (JAMP Pharma Corporation) with ^{Pr}PERIOSTAT® Capsules, 20 mg (PENDOPHARM, Division of Pharmascience Inc.) was conducted in healthy, adult, male and female subjects under fasting conditions. Comparative bioavailability data from the 23 subjects that were included in the statistical analysis are presented in the following table:

SUMMARY TABLE OF THE COMPARATIVE BIOAVAILABILITY DATA

Doxycycline (1 x 20 mg) Geometric Mean Arithmetic Mean (CV %)				
Parameter	Test[1]	Reference[2]	% Ratio of Geometric Means	90% Confidence Interval
AUC_T (ng·h/mL)	9075.34 9169.82 (15.52)	9261.85 9381.13 (17.69)	98.0	93.0 - 103.2
AUC_I (ng·h/mL)	9929.94 10027.56 (15.49)	10114.35 10238.61 (16.94)	98.2	92.9 - 103.8
C_{max} (ng/mL)	553.68 562.35 (18.00)	592.92 609.37 (26.05)	93.4	87.0 – 100.2
T_{max}[3] (h)	1.33 (0.75 - 4.03)	1.00 (0.75 - 2.33)		
$T_{½}$[4] (h)	20.16 (22.40)	20.03 (21.14)		

[1] JAMP Doxycycline (doxycycline hyclate) (JAMP Pharma Corporation).
[2] ^{Pr}PERIOSTAT® (doxycycline hyclate), 20 mg capsules (PENDOPHARM, Division of Pharmascience Inc.).
[3] Expressed as the median (range) only.
[4] Expressed as the arithmetic mean (CV%) only.

TOXICOLOGY

Acute Toxicity

The acute oral and parenteral toxicity of doxycycline in mice, rats and dogs are as follows:

	LD_{50} (95% confidence limits) mg/kg oral	
	Oral	**I.V.**
Mice	1,900 (1696-2128)	241 (230-253)
Rats	> 2,000	228 (202-258)
Dogs	> 500	> 100

The intraperitoneal LD_{50}'s of doxycycline in weanling and newborn rats are 262 (222-309) and 300 (275-327) mg/kg, respectively.

Reproductive Toxicity and Teratology

Doxycycline has no teratologic effects in rats, rabbits or monkeys.

Breeding rats received doxycycline by gavage in doses of 50 and 250 mg/kg/day prior to and throughout two consecutive litters. There was no evidence that doxycycline interfered with the reproductive process in rats.

Pregnant female white New Zealand rabbits received doxycycline orally in doses of 8 and 40 mg/kg/day, respectively, from day 8 to day 16 of pregnancy. Spina bifida and partial anencephaly in one pup each in the control and the 8 mg/kg group, respectively, are believed to be spontaneous and drug-induced.

In teratogenic studies using a limited number of monkeys, doxycycline, in doses ranging from 1 to 50 mg/kg/day, did not product any teratologic effects.

Carcinogenesis and Mutagenesis

Doxycycline hyclate was evaluated in a long-term animal study, no evidence of carcinogenic potential was obtained.

Doxycycline hyclate demonstrated no potential to cause genetic toxicity in an *in vitro* point mutation study with mammalian cells (CHO/HGPRT forward mutation assay) or in an *in vivo* micronucleus assay conducted in CD-1 mice. However, data from an *in vitro* assay with CHO cells for potential to cause chromosomal aberrations suggests that doxycycline hyclate is a weak clastogen.

Oral administration of doxycycline hyclate to male and female Sprague-Dawley rats adversely affected fertility and reproductive performance, as evidenced by increased time for mating to occur, reduced sperm motility, velocity, and concentration, abnormal sperm morphology, and increased pre-and post-implantation losses. Doxycycline hyclate induced reproductive toxicity at all dosages that were examined in this study, as even the lowest dosage tested (50 mg/kg/day) induced a statistically significant reduction in sperm velocity. Note that 50 mg/kg/day is approximately 10 times the amount of doxycycline hyclate contained in the recommended daily dose of doxycycline hyclate for a 60 kg human when compared on the basis of body surface area estimates (mg/m^2). Although doxycycline impairs the fertility of rats when administered at sufficient dosage, the effect of doxycycline hyclate on human fertility is unknown.

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11. Twice daily (BID) doses of doxycycline 20 mg or tetracycline 100 mg or no treatment for 4 weeks. (Part III - Vol 4, pg. 124 / Part IV - Vol 108, pg. 53).

12. A bioavailability and dose proportionality study of three dosing levels of doxycycline capsules in normal healthy male volunteers. (Part III - Vol 4, pg. 93 / Part IV - Vol 11, pg. 18 & Vol 13, pg. 1).

13. A double blind, single dose , 2-period crossover pharmacokinetic study in healthy volunteers. (Part III - Vol 4, pg. 94 / Part IV - Vol 11, pg. 26 & Vol 14-16).

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23. Mouse Micronucleous test (Part III - Vol 4, pg. 74 / Part IV - Vol 10, pg. 276).

24. *In vitro* mammalian cell cytogenetic test - CHO cells (Part III - Vol 4, pg. 72 / Part IV - Vol 10, pg. 251).

25. Comprehensive Summary (Part III - Vol 4, pg. 79 / Part IV - Vol 5, pg. 192).

26. Product Monograph - PrPERIOSTAT® (Doxycycline Hyclate Capsules, USP, 20 mg) PENDOPHARM, Division of Pharmascience Inc., Date of Revision: November 14, 2018, Control: 215842

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

PrJAMP Doxycycline
Doxycycline Capsules USP

Read this carefully before you start taking JAMP Doxycycline 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 JAMP Doxycycline.

What is JAMP Doxycycline used for?
JAMP Doxycycline is used in adults with gum disease (periodontitis) after a certain dental procedure (scaling and root planing). It helps to improve tooth attachment and reduce gum pockets.

JAMP Doxycycline contains an antibacterial ingredient called doxycycline that is also used to treat bacterial infections.

How does JAMP Doxycycline work?
JAMP Doxycycline belongs to the class of antibiotics known as tetracyclines. It may help to prevent the breakdown of gum tissue.

What are the ingredients in JAMP Doxycycline?
Medicinal ingredient: Doxycycline (as doxycycline hyclate)

Non-medicinal ingredients: Black iron oxide, croscarmellose sodium, gelatin, lactose monohydrate, magnesium stearate, propylene glycol, potassium hydroxide, shellac, stearic acid, titanium dioxide.

JAMP Doxycycline comes in the following dosage forms:
Capsules; 20 mg

Do not use JAMP Doxycycline if you:
- Are allergic or hypersensitive to doxycycline or any other tetracycline antibiotic
- Have the autoimmune disease myasthenia gravis, which causes severe weakness in the muscles used for breathing and moving parts of the body
- Are pregnant or planning to become pregnant. Using JAMP Doxycycline during pregnancy can cause birth defects. It can also cause damage and discolouration to your unborn babies developing teeth
- Are breastfeeding or planning to breastfeed. Doxycycline hyclate can pass into breastmilk and cause damage and discolouration to your babies developing teeth.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JAMP Doxycycline. Talk about any health conditions or problems you may have, including if you:
- Are taking medicines to thin the blood, used to prevent blood clots
- You are taking other antibiotics, such as penicillin
- Have a history of oral thrush (yeast infection in your mouth and/or throat) or are at risk for this type of infection.

Other warnings you should know about:
Sun Sensitivity
JAMP Doxycycline can cause your skin to become sensitive to the sun. While taking JAMP Doxycycline, use sunscreen and protective clothing if you are going to be in direct sunlight and avoid tanning beds and other sources of UV light. If you notice any skin redness after being in the sun while taking JAMP Doxycycline contact your healthcare professional immediately.

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 JAMP Doxycycline:
- Antacids, used to treat heartburn and indigestion that contain aluminum, calcium, magnesium or bismuth subsalicylate
- Iron-containing preparations, such as iron supplements
- Medicines to thin the blood, used to prevent blood clots
- Antibiotics, used to treat bacterial infections, such as penicillin, tetracycline and methoxyfluorane
- Barbiturates used to treat insomnia and anxiety, such as phenobarbital
- Anti-seizure medicines, such as carbamazepine and phenytoin
- Oral birth control pills.

How to take JAMP Doxycycline:
- Take JAMP Doxycycline twice a day, at least one hour before your morning and evening meals
- JAMP Doxycycline capsules should be swallowed with a full glass of water
- Although you may feel better early in treatment, JAMP Doxycycline should be used exactly as directed by your healthcare professional
- Misuse or overuse of JAMP Doxycycline could lead to the growth of bacteria that will not be killed by doxycycline (resistance). This means that doxycycline will not work for you in the future
- Do not share your medicine.

Usual Adult Dose:
- 20 mg twice a day for up to 9 months

Overdose:

If you think you, or a person you are caring for, have taken too much JAMP Doxycycline, contact your healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using JAMP Doxycycline?
These are not all the possible side effects you may feel when taking JAMP Doxycycline. If you experience any side effects not listed here, contact your healthcare professional.
Side effects may include:
- Headache

- Common cold (runny nose, sneezing, cough, sore throat)
- Flu symptoms (fever, body aches, headache, cough, sore throat)
- Sinus infection (sinusitis), sinus congestion, sinus headache
- Toothache or other tooth problem
- Gum pain
- Nausea, indigestion
- Diarrhea
- Joint pain, back pain/ache, muscle pain
- Rash
- Menstrual cramps.

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	
Gum abscess: gum swelling, red tender gums, throbbing pain, tooth sensitivity, pus discharge, fever		√	
Bronchitis: cough with mucus, fatigue, shortness of breath, fever, chills, chest discomfort		√	
Oral yeast infection (thrush): creamy white bumps on the tongue, inner cheeks, gums or tonsils that bleed when scraped, pain, difficulty swallowing		√	
Vaginal yeast infection: vaginal itching or burning, thick white "cottage cheese" like discharge, vaginal redness or swelling, stinging or burning when urinating or during sex		√	

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:

- Stored at room temperatures of 15°C - 30°C in a tight, light-resistant container.
- Protected from excessive humidity.
- Keep out of reach and sight or children.

If you want more information about JAMP Doxycycline:

- 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.jamppharma.com), or by calling 1-866-399-9091.

This leaflet was prepared by:
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