HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use XIMINO safely and effectively. See full prescribing information for XIMINO.

XIMINO® (minocycline hydrochloride) extended-release capsules, for oral use

Initial U.S. Approval: 1971

----------INDICATIONS AND USAGE----------

XIMINO is a tetracycline-class drug indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. (1)

Limitations of Use

This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria and to maintain the effectiveness of other antibacterial drugs, use XIMINO only as indicated. (1)

----------DOSAGE AND ADMINISTRATION----------

The recommended dosage of XIMINO is approximately 1 mg/kg once daily for 12 weeks. (2)

----------DOSAGE FORMS AND STRENGTHS----------

Extended-release capsules: 45 mg, 90 mg, and 135 mg (3)

----------CONTRAINDICATIONS----------

Known hypersensitivity to any of the tetracyclines. (4)

----------WARNINGS AND PRECAUTIONS----------

- *Serious Skin/Hypersensitivity Reactions*: Minocycline has been associated with anaphylaxis, serious skin reactions, erythema multiforme, and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome. Discontinue XIMINO immediately if symptoms occur. (5.1)
- *Tooth Discoloration and Enamel Hypoplasia:* Use during the second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia. (5.2, 8.1, 8.4)
- *Inhibition of Bone Growth:* Use during the second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years may cause reversible inhibition of bone growth. (5.3, 8.1, 8.4)
- *Clostridioides difficile-Associated Diarrhea (Antibiotic-Associated Colitis)*: Discontinue XIMINO if *Clostridioides difficile*-associated diarrhea occurs. (5.4)
- *Hepatotoxicity*: Discontinue XIMINO if liver injury is suspected. (5.5)
- *Central Nervous System Effects:* May cause central nervous system side effects including light-headedness, dizziness, or vertigo. (5.6)
- *Idiopathic Intracranial Hypertension:* May cause idiopathic intracranial hypertension in adults and adolescents. Discontinue XIMINO if symptoms occur. (5.7)
- *Autoimmune Syndromes:* Minocycline has been associated with autoimmune syndromes; discontinue XIMINO immediately if symptoms occur. (5.8)
- *Metabolic Effects:* If renal impairment exists, reduce XIMINO dosage. (5.9)

----------ADVERSE REACTIONS----------

The most commonly observed adverse reactions (incidence ≥ 5%) are fatigue, dizziness, and pruritus. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-406-7984 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

----------DRUG INTERACTIONS----------

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage. (7.1)

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Breastfeeding is not recommended. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised:1/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

XIMINO is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Limitations of Use

- XIMINO did not demonstrate any effect on non-inflammatory acne lesions.
- This formulation of minocycline has not been evaluated in the treatment of infections *[see Clinical Studies (14)]*.
- To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, use XIMINO only as indicated *[see Warnings and Precautions (5.12)]*.

2 DOSAGE AND ADMINISTRATION

The recommended dosage of XIMINO is approximately 1 mg/kg once daily for 12 weeks. Table 1 provides the recommended XIMINO dosage based upon weight ranges.

Table 1: Dosing Table for XIMINO

Patient's Weight (kg)	Recommended Dosage (mg/day)
45 to 59	45
60 to 90	90
91 to 136	135

Higher dosages have not shown to be of additional benefit in the treatment of inflammatory lesions of acne and may be associated with more acute vestibular adverse reactions.

Swallow capsules whole. Do not split, crush, or chew the extended-release capsules.

Administer XIMINO with or without food *[see Clinical Pharmacology (12.3)]*. Ingestion of food along with XIMINO may help reduce the risk of esophageal irritation and ulceration.

In patients with renal impairment, decrease the daily dosage by either reducing the recommended individual doses and/or by extending the time intervals between doses *[see Warnings and Precautions (5.9)]*.

3 DOSAGE FORMS AND STRENGTHS

- 45 mg extended-release capsules: opaque bluish green cap and opaque yellow body hard gelatin capsule with 'RI18' imprinted on both cap and body in black ink containing one plain to mottled, yellow to grayish yellow colored film-coated, round tablet plain on both sides.
- 90 mg extended-release capsules: opaque light blue cap and body hard gelatin capsule with 'RI19' imprinted on both cap and body in black ink containing two plain to mottled, yellow to grayish yellow colored film-coated, round tablets plain on both sides.
- 135 mg extended-release capsules: opaque bluish green cap and opaque light blue body hard gelatin capsule with 'RI20' imprinted on both cap and body in black ink containing three

plain to mottled, yellow to grayish yellow colored film-coated, round tablets plain on both sides.

4 CONTRAINDICATIONS

XIMINO is contraindicated in patients with a history of a hypersensitivity reaction to any of the tetracyclines *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Skin/Hypersensitivity Reactions

Cases of anaphylaxis, serious skin reactions (e.g., Stevens Johnson syndrome), erythema multiforme, and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome have been reported postmarketing with minocycline use in patients with acne. DRESS syndrome consists of cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, and one or more of the following visceral complications such as: hepatitis, pneumonitis, nephritis, myocarditis, and pericarditis. Fever and lymphadenopathy may be present. In some cases, death has been reported. If this syndrome is recognized, immediately discontinue XIMINO.

5.2 Tooth Discoloration and Enamel Hypoplasia

The use of tetracycline-class drugs, including XIMINO, during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). Permanent discoloration of the teeth is more common during long-term use of tetracycline class drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Use of XIMINO is not recommended during tooth development.

Advise the patient of the potential risk to the fetus if XIMINO is used during the second or third trimester of pregnancy *[see Use in Specific Populations (8.1, 8.4)]*.

5.3 Inhibition of Bone Growth

The use of tetracycline-class drugs, including XIMINO, during the second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years may cause reversible inhibition of bone growth. All tetracyclines, including XIMINO, form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Advise the patient of the potential risk to the fetus if XIMINO is used during the second or third trimester of pregnancy *[see Use in Specific Populations (8.1, 8.4)]*.

5.4 *Clostridioides difficile*-Associated Diarrhea (Antibiotic-Associated Colitis)

Clostridioides difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents, including minocycline, and may range in severity from mild diarrhea to fatal colitis.

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 antibiotic use. 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, discontinued XIMINO.

5.5 Hepatotoxicity

Postmarketing cases of serious liver injury, including irreversible drug-induced hepatitis and fulminant hepatic failure (sometimes fatal) have been reported with minocycline use in the treatment of acne. Discontinue XIMINO If liver injury is suspected.

5.6 Central Nervous System Effects

Central nervous system side effects including light-headedness, dizziness, or vertigo have been reported with minocycline therapy. Caution patients who experience these symptoms about driving vehicles or using hazardous machinery while on XIMNO. These symptoms may disappear during therapy and usually rapidly disappear when XIMINO is discontinued.

5.7 Idiopathic Intracranial Hypertension

Idiopathic Intracranial hypertension has been associated with the use of tetracycline-class drugs, including XIMINO. Clinical manifestations of idiopathic intracranial hypertension 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 idiopathic intracranial hypertension are at a greater risk for developing idiopathic intracranial hypertension. Avoid concomitant use of isotretinoin and XIMINO because isotretinoin, a systemic retinoid, is also known to cause idiopathic intracranial hypertension.

Permanent visual loss may exist, even after the medication is discontinued. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Because intracranial pressure can remain elevated for weeks after drug cessation, monitor patients until they stabilize.

5.8 Autoimmune Syndromes

Tetracyclines have been associated with the development of autoimmune syndromes. The long-term use of minocycline in the treatment of acne has been associated with drug-induced lupus-like syndrome, autoimmune hepatitis, and vasculitis. Sporadic cases of serum sickness have presented shortly after minocycline use. Symptoms may be manifested by fever, rash, arthralgia, and malaise. Evaluate symptomatic patients. If symptoms occur, immediately discontinue use of XIMINO.

5.9 Metabolic Effects

The anti-anabolic action of the tetracyclines, including XIMINO, may cause an increase in blood urea nitrogen (BUN). In patients with significantly impaired renal function, higher serum levels of tetracycline-class drugs may lead to azotemia, hyperphosphatemia, and acidosis. If renal impairment exists, lower the total doses of XIMINO, and if therapy is prolonged, monitor serum levels of XIMINO.

5.10 Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including minocycline. Advise patients to minimize or avoid

exposure to natural or artificial sunlight (e.g., tanning beds or UVA/B treatment) while using XIMINO. Instruct patients to use sunscreen products and wear protective apparel (e.g., hat) when exposure to sun cannot be avoided.

5.11 Tissue Hyperpigmentation

Tetracycline-class antibiotics are known to cause hyperpigmentation. Tetracycline therapy may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (e.g., teeth, mucosa, alveolar bone), sclerae, and heart valves. Skin and oral pigmentation has been reported to occur independently of time or amount of drug administration, whereas other tissue pigmentation has been reported to occur upon prolonged administration. Skin pigmentation includes diffuse pigmentation as well as over sites of scars or injury.

5.12 Development of Drug-Resistant Bacteria

Bacterial resistance to the tetracyclines may develop in patients using XIMINO. Because of the potential for drug-resistant bacteria to develop during the use of XIMINO, use XIMINO only as indicated.

5.13 Superinfection

Use of XIMINO may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue XIMINO and institute appropriate therapy.

5.14 Laboratory Monitoring

Perform periodic laboratory evaluations of organ systems, including hematopoietic, renal, and hepatic studies.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Serious Skin/Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*
- *Clostridioides difficile*-Associated Diarrhea (Antibiotic-Associated Colitis) *[see Warnings and Precautions (5.4)]*
- Hepatotoxicity *[see Warnings and Precautions (5.5)]*
- Central Nervous System Effects *[see Warnings and Precautions (5.6)]*
- Idiopathic Intracranial Hypertension *[see Warnings and Precautions (5.7)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following table summarizes selected adverse reactions reported in clinical trials at a rate of ≥ 1% for XIMINO and higher than placebo.

Table 2: Selected Treatment-Emergent Adverse Reactions in at least 1% of Clinical Trial Subjects and Higher than Placebo

Adverse Reactions	Minocycline hydrochloride (1 mg/kg) N = 674 (%)	PLACEBO N = 364 (%)
At least one treatment-emergent event	379 (56)	197 (54)

Fatigue	62 (9)	24 (7)
Dizziness	59 (9)	17 (5)
Pruritus	31 (5)	16 (4)
Malaise	26 (4)	9 (3)
Somnolence	13 (2)	3 (1)
Urticaria	10 (2)	1 (0)
Tinnitus	10 (2)	5 (1)
Arthralgia	9 (1)	2 (0)
Vertigo	8 (1)	3 (1)

6.2 Postmarketing Experience

The following adverse reactions have been reported with minocycline hydrochloride use in a variety of indications. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Skin and hypersensitivity reactions: anaphylaxis, angioedema, DRESS syndrome, erythema multiforme, Stevens-Johnson syndrome, acute febrile neutrophilic dermatosis (Sweet's syndrome), fixed drug eruptions, balanitis, anaphylactoid purpura, photosensitivity, pigmentation of skin and mucous membranes.

Autoimmune conditions: polyarthralgia, pericarditis, exacerbation of systemic lupus, pulmonary infiltrates with eosinophilia, lupus-like syndrome.

Central nervous system: idiopathic intracranial hypertension, bulging fontanels in infants, decreased hearing.

Endocrine: brown-black microscopic thyroid discoloration, abnormal thyroid function.

Oncology: thyroid cancer.

Oral: glossitis, dysphagia, tooth discoloration.

Gastrointestinal: enterocolitis, pancreatitis, hepatitis, liver failure.

Renal: acute renal failure.

Hematology: hemolytic anemia, thrombocytopenia, eosinophilia.

7 DRUG INTERACTIONS

7.1 Anticoagulants

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

7.2 Penicillin

Because bacteriostatic drugs may interfere with the bactericidal action of penicillin, avoid giving XIMINO in conjunction with penicillin.

7.3 Antacids and Iron Preparations

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

7.4 Drug/Laboratory Test Interactions

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Tetracycline-class drugs, including XIMINO, may cause permanent discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the second and third trimesters of pregnancy *[see Warnings and Precautions (5.2, 5.3) and Use in Specific Populations (8.4)]*. A few postmarketing cases of limb reductions have been reported over decades of use; however, the association is unclear. The limited data from postmarketing reports are not sufficient to inform a drug-associated risk for birth defects or miscarriage.

In animal reproduction studies conducted in pregnant rats and rabbits, fetuses with bent limb bones were observed following oral administration of minocycline during organogenesis at systemic exposures 3 and 2 times, respectively, the exposure associated with the maximum recommended human dose (MRHD) *(see Data).*

If a patient becomes pregnant while taking XIMINO, advise the patient of the risk to the fetus and to discontinue treatment.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

The use of tetracycline-class drugs, including XIMINO, during tooth development (second and third trimesters, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). Permanent discoloration of the teeth is more common during long-term use of the drug but has been observed following repeated short-term courses *[see Warnings and Precautions (5.2)]*.

Animal Data

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause delayed skeletal development in the developing fetus. Evidence of embryotoxicity has been noted in animals treated early in pregnancy *[see Warnings and Precautions (5.3)]*.

Minocycline induced skeletal malformations (bent limb bones) in fetuses when administered to pregnant rats and rabbits during the period of organogenesis at doses of 30 mg/kg/day and 100 mg/kg/day, respectively, (3 and 2 times the MRHD on an AUC comparison basis, respectively). Reduced mean fetal body weight was observed in studies in which minocycline was administered to pregnant rats at an oral dose of 10 mg/kg/day (approximately equal to the MRHD on an AUC comparison basis).

Minocycline was assessed for effects on peri- and post-natal development of rats in a study that involved oral administration to pregnant rats during the period of organogenesis through

lactation at doses of 5, 10, or 50 mg/kg/day. In this study, body weight gain was significantly reduced in pregnant females that received 50 mg/kg/day (2.5 times the MRHD on an AUC comparison basis). No effects of treatment on the duration of the gestation period or the number of live pups born per litter were observed. Gross external anomalies observed in offspring of animals that received minocycline included reduced body size, improperly rotated forelimbs, and reduced size of extremities. No effects were observed on the physical development, behavior, learning ability, or reproduction of the offspring of animals that received minocycline.

8.2 Lactation

Risk Summary

Tetracycline-class antibiotics, including minocycline, are present in human milk following oral administration. There are no data on the effects of minocycline on milk production. Because of the potential for serious adverse reactions, including tooth discoloration and inhibition of bone growth, advise patients that breastfeeding is not recommended during treatment with XIMINO and for 4 days after the final dose *[see Warnings and Precautions (5.2, 5.3)]*.

8.4 Pediatric Use

The safety and effectiveness of XIMINO have been established in pediatric patients 12 years of age and older for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris *[see Clinical Studies (14)]*. Tooth discoloration and inhibition of bone growth have been observed in pediatric patients *[see Warnings and Precaution (5.2, 5.3)]*. Use of tetracycline-class antibiotics below the age of 8 is not recommended due to the potential for tooth discoloration *[see Warnings and Precautions (5.2)]*.

Safety and effectiveness of XIMINO have not been established in pediatric patients younger than 12 years of age.

8.5 Geriatric Use

Clinical studies of XIMINO did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and concomitant disease or other drug therapy.

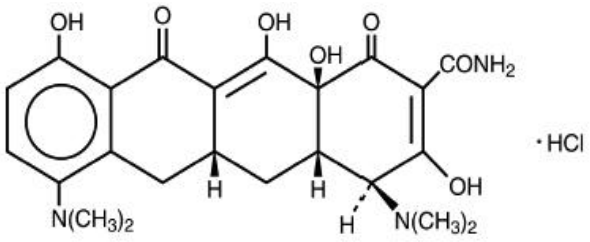
10 OVERDOSAGE

Minocycline is not removed in significant quantities by hemodialysis or peritoneal dialysis. In case of overdosage, discontinue XIMINO, treat symptomatically and institute supportive measures. Call Poison Control Center at 1-800-222-1222 for the latest recommendations.

11 DESCRIPTION

The active ingredient in XIMINO extended-release capsules is minocycline hydrochloride, a semi synthetic derivative of tetracycline. XIMINO is a tetracycline-class drug. XIMINO is known chemically as [4*S*-(4α,4aα,5aα,12aα)]-4,7-Bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-2-naphthacenecarboxamide mono hydrochloride.

The structural formula is represented below:



$C_{23}H_{27}N_3O_7$•HCl M.W. 493.95

Minocycline hydrochloride, USP is a yellow crystalline powder, sparingly soluble in water, soluble in solutions of alkali hydroxides and carbonates, slightly soluble in alcohol, practically insoluble in chloroform and in ether.

XIMINO (minocycline hydrochloride) extended-release capsules for oral administration contain minocycline hydrochloride, USP equivalent to 45 mg, 90 mg, or 135 mg of minocycline. The extended-release capsules contain the following inactive ingredients: colloidal silicon dioxide, D&C Yellow #10 (in 45 mg strength), FD&C Blue #1, FD&C Yellow #6 (in 45 mg and 135 mg strength), gelatin, hypromellose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate, and titanium dioxide.

The 45 mg, 90 mg, and 135 mg capsules also contain Opadry Clear which contains hypromellose, polyethylene glycol 400, polyethylene glycol 6000, and talc.

XIMINO extended-release capsules also contain black ink which contains ferrosoferric oxide, potassium hydroxide, propylene glycol, and shellac.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
The mechanism of action of XIMINO for the treatment of acne is unknown.

12.2 Pharmacodynamics
The pharmacodynamics of XIMINO for the treatment of acne are unknown.

12.3 Pharmacokinetics
XIMINO is not bioequivalent to immediate release minocycline products.

Following administration of a single dose of XIMINO (135 mg) to 32 healthy male and female adult subjects, the mean (SD) $AUC_{(0-\infty)}$ and C_{max} were 17.90 (5.56) mcg x hr/mL and 0.96 (0.32) mcg/mL, respectively, under fasting conditions.

In a separate trial, when a single dose of XIMINO (135 mg) was administered with a high fat meal to 30 healthy male and female adult subjects, the mean (SD) $AUC_{(0-\infty)}$ and C_{max} were 17.16 (3.19) mcg x hr/mL and 0.97 (0.25) mcg/mL, respectively.

Minocycline is lipid soluble and distributes into the skin and sebum.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a carcinogenicity study in which minocycline hydrochloride was orally administered to male and female rats once daily for up to 104 weeks at dosages up to 200 mg/kg/day, minocycline hydrochloride was associated in both sexes with follicular cell tumors of the thyroid gland, including increased incidences of adenomas, carcinomas and the combined incidence of adenomas and carcinomas in males, and adenomas and the combined incidence of adenomas and carcinomas in females. In a carcinogenicity study in which minocycline hydrochloride was orally administered to male and female mice once daily for up to 104 weeks at dosages up to 150 mg/kg/day, exposure to minocycline hydrochloride did not result in a significantly increased incidence of neoplasms in either males or females.

Minocycline was not mutagenic in vitro in a bacterial reverse mutation assay (Ames test) or CHO/HGPRT mammalian cell assay in the presence or absence of metabolic activation. Minocycline was not clastogenic in vitro using human peripheral blood lymphocytes or in vivo in a mouse micronucleus test.

Male and female reproductive performance in rats was unaffected by oral doses of minocycline of up to 300 mg/kg/day (40 times the MRHD on an AUC comparison basis). However, oral administration of 100 or 300 mg/kg/day of minocycline to male rats (15 to 40 times the MRHD on an AUC comparison basis) adversely affected spermatogenesis. Effects observed at 300 mg/kg/day included a reduced number of sperm cells per gram of epididymis, an apparent reduction in the percentage of sperm that were motile, and (at 100 and 300 mg/kg/day) increased numbers of morphologically abnormal sperm cells. Morphological abnormalities observed in sperm samples included absent heads, misshapen heads, and abnormal flagella.

14 CLINICAL STUDIES

The safety and efficacy of minocycline hydrochloride in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris was assessed in two 12-week, multi-center, randomized, double-blind, placebo-controlled, trials in adult and pediatric subjects 12 years of age and older (Trial 1 and Trial 2). A total of 924 subjects with non-nodular moderate to severe acne vulgaris received minocycline hydrochloride or placebo for a total of 12 weeks.

The mean age of subjects was 20 years and subjects were from the following racial groups: White (73%), Hispanic (13%), Black (11%), Asian/Pacific Islander (2%), and Other (2%).
The two primary efficacy endpoints were:

1) Mean percent change in inflammatory lesion counts from Baseline to 12 weeks.
2) Percentage of subjects with an Evaluator's Global Severity Assessment (EGSA) of clear or almost clear at 12 weeks.

Efficacy results are presented in Table 4.

Table 4: Efficacy Results at Week 12 in Subjects with Non-nodular Moderate to Severe Acne Vulgaris in Trial 1 and Trial 2

	Trial 1		**Trial 2**	
	Minocycline hydrochloride (1 mg/kg) N = 300	**Placebo N = 151**	**Minocycline hydrochloride (1 mg/kg) N = 315**	**Placebo N = 158**

Mean percent improvement in inflammatory lesions	43.1%	31.7%	45.8%	30.8%
No. (%) of subjects clear or almost clear on the EGSA*	52 (17.3%)	12 (7.9%)	50 (15.9%)	15 (9.5%)

*Evaluator's Global Severity Assessment

Minocycline hydrochloride did not demonstrate any effect on non-inflammatory lesions (benefit or worsening).

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

XIMINO (minocycline hydrochloride) extended-release capsules are hard-gelatin capsules containing minocycline hydrochloride, USP equivalent to 45 mg, 90 mg, or 135 mg minocycline. The extended-release capsules are supplied as follows:

- 45 mg extended-release capsules: opaque bluish green cap and opaque yellow body hard gelatin capsule with 'RI18' imprinted on both cap and body in black ink containing one plain to mottled, yellow to grayish yellow colored film-coated, round tablet plain on both sides and are supplied as follows:

  NDC 10631-330-30 Bottle of 30
  NDC 10631-330-05 Bottle of 500
  NDC 10631-330-69 Blister pack of 10

- 90 mg extended-release capsules: opaque light blue cap and body hard gelatin capsule with 'RI19' imprinted on both cap and body in black ink containing two plain to mottled, yellow to grayish yellow colored film-coated, round tablets plain on both sides and are supplied as follows:

NDC 10631-331-30	Bottle of 30
NDC 10631-331-05	Bottle of 500
NDC 10631-331-69	Blister pack of 10

- 135 mg extended-release capsules**:** opaque bluish green cap and opaque light blue body hard gelatin capsule with 'RI20' imprinted on both cap and body in black ink containing three plain to mottled, yellow to grayish yellow colored film-coated, round tablets plain on both sides and are supplied as follows:

NDC 10631-332-30	Bottle of 30
NDC 10631-332-05	Bottle of 500
NDC 10631-332-69	Blister pack of 10

Storage

Store at 20º C - 25º C (68º F - 77° F); excursions are permitted to 15° C - 30° C (59° F - 86° F) [See USP Controlled Room Temperature].

Handling

Protect from light, moisture, and excessive heat.

Dispense in tight, light-resistant container with child-resistant closure.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Patients taking XIMINO should receive the following information and instructions:

Administration Instructions

- XIMINO should be taken exactly as directed.
- Advise patients to swallow XIMINO whole and not to chew, crush, or split the capsules *[see Dosage and Administration (2)]*.

Serious Skin/Hypersensitivity Reactions

- Inform patients that serious skin reactions have occurred with the minocycline use in patients with acne. Advise patients to discontinue use of XIMINO and contact their healthcare provider immediately at the first evidence of skin erythema *[see Warnings and Precautions (5.1)]*.

Tooth Discoloration and Enamel Hypoplasia

- Advise patients that XIMINO use in pregnancy may cause permanent tooth discoloration of deciduous teeth. Advise patients to discontinue XIMINO during pregnancy and to inform

their healthcare provider right away if they become pregnant during treatment *[see Warnings and Precautions (5.2), Use in Specific Populations (8.1)]*.

- Advise caregivers of pediatric patients that XIMINO use may cause permanent discoloration of deciduous and permanent teeth *[see Warnings and Precautions (5.2), Use in Specific Populations (8.4)]*.

Inhibition of Bone Growth

- Advise patients that XIMINO use in pregnancy may cause inhibition of fetal bone growth. Advise patients to discontinue XIMINO during pregnancy and to inform their healthcare provider right away if they become pregnant during treatment *[see Warnings and Precautions (5.3), Use in Specific Populations (8.1)]*.

Clostridioides difficile-Associated Diarrhea (Antibiotic-Associated Colitis)

- Advise patients that *Clostridioides difficile*-associated diarrhea (antibiotic-associated colitis) can occur with minocycline therapy, including XIMINO. If patients develop watery or bloody stools, advise patients to seek medical attention *[see Warnings and Precautions (5.4)]*.

Hepatotoxicity

- Inform patients about the possibility of hepatotoxicity. Advise patients to seek medical advice if they experience signs or symptoms of hepatotoxicity, including loss of appetite, tiredness, diarrhea, skin turning yellow, bleeding easily, confusion, and sleepiness *[see Warnings and Precautions (5.5)]*.

Central Nervous System Effects

- Inform patients that central nervous system adverse reactions including dizziness or vertigo have been reported with oral minocycline therapy. Caution patients about driving vehicles or using hazardous machinery if they experience such symptoms while on XIMINO *[see Warnings and Precautions (5.6)]*.

Idiopathic Intracranial Hypertension

- Inform patients that idiopathic intracranial hypertension can occur with minocycline therapy. Advise patients to seek medical attention if they develop unusual headache, visual symptoms, such as blurred vision, diplopia, and vision loss *[see Warnings and Precautions (5.7)]*.

Autoimmune Syndromes

- Inform patients that autoimmune syndromes, including drug-induced lupus-like syndrome, autoimmune hepatitis, vasculitis, and serum sickness have been observed with tetracycline-class drugs, including minocycline. Symptoms may be manifested by arthralgia, fever, rash, and malaise. Advise patients who experience such symptoms to immediately discontinue XIMINO and seek medical help *[see Warnings and Precautions (5.8)]*.

Photosensitivity

- Inform patients that photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including minocycline. Advise patients to minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using XIMINO. Instruct patients to use sunscreen and wear protective clothing (e.g., hat) when exposure to sun cannot be avoided *[see Warnings and Precautions (5.10)]*.

Tissue Hyperpigmentation

- Inform patients that XIMINO may cause discoloration of skin, scars, teeth, or gums *[see Warnings and Precautions (5.11)]*.

Lactation

- Advise patients that XIMINO therapy is not recommended during breastfeeding and for 4 days after the final dose *[see Use in Specific Populations (8.2)]*.

XIMINO is a registered trademark of Journey Medical Corp.

Manufactured by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

Distributed by:
Journey Medical Corp.
Scottsdale, AZ 85258

Issued May 2019 FDA-13

PATIENT INFORMATION
XIMINO® (Zī-min-o)
(minocycline hydrochloride)
extended-release capsules

What is XIMINO?

XIMINO is prescription medicine used to treat pimples and red bumps (non-nodular inflammatory lesions) that happen with moderate to severe acne vulgaris in people 12 years and older.

XIMINO is not effective for acne that is not red-looking (this means acne that is not inflammatory).

It is not known if XIMINO is safe and effective for the treatment of infections.
It is not known if XIMINO is safe and effective in children under the age of 12 years.

Who should not take XIMINO?

Do not take XIMINO if you are allergic to tetracycline medicines. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Before you take XIMINO, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have liver problems
- have diarrhea or watery stools
- have vision problems
- are pregnant or plan to become pregnant. XIMINO may harm your unborn baby. Taking XIMINO while you are pregnant may cause serious side effects on the growth of bone and teeth of your baby. Stop taking XIMINO and call your healthcare provider right away if you become pregnant during treatment with XIMINO.
- are breastfeeding or plan to breastfeed. XIMINO can pass into your breast milk and may harm your baby. You should not breastfeed during treatment with XIMINO and for 4 days after the final dose.

Tell your healthcare provider about all the other medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements**.** XIMINO and other medicines may affect each other causing serious side effects.

Especially tell your healthcare provider if you take:

- blood thinner medicine
- a penicillin antibiotic medicine
- antacids that contain aluminum, calcium, or magnesium or iron-containing products
- a medicine taken by mouth that contains isotretinoin

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take XIMINO?

- Take XIMINO exactly as your healthcare provider tells you.
- Swallow XIMINO capsules whole. Do not split, crush, or chew the capsules.
- Take XIMINO with or without food**.** Taking XIMINO with food may reduce your risk of getting irritation or ulcers in your esophagus. Your esophagus is the tube that connects your mouth to your stomach.
- If you take too much XIMINO, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking XIMINO?

- Limit or avoid sunlight or artificial sunlight, such as sunlamps, or tanning beds during treatment with XIMINO. XIMINO can make your skin sensitive to the sun and you may sunburn more easily. Use sunscreen and wear protective clothing to help protect against sunburn if you have to be in the sunlight during treatment with XIMINO.
- XIMINO may cause you to feel dizzy, lightheaded, or have a spinning feeling (vertigo). You should not drive or operate dangerous machinery until you know how XIMINO affects you.

What are possible side effects of XIMINO?
XIMINO may cause serious side effects, including:

- **Serious skin and allergic reactions** that may affect parts of your body such as your liver, lungs, kidneys and heart. Sometimes these can lead to death. Stop taking XIMINO and go to the nearest hospital emergency room right away if you have any of the following signs or symptoms:
  - skin rash, hives, sores in your mouth, or your skin blisters and peels
  - swelling of your face, eyes, lips, tongue, or throat
  - trouble swallowing or breathing
  - blood in your urine
  - fever, yellowing of the skin or the whites of your eyes, dark colored urine
  - pain on the right side of the stomach area (abdominal pain)
  - chest pain or abnormal heartbeats
  - swelling in your legs, ankles, and feet
- **Harm to an unborn baby.** See "**Before you take XIMINO, tell your healthcare provider about all of your medical conditions, including if you:**"
- **Permanent teeth discoloration.** XIMINO may permanently turn a baby or child's teeth yellow-gray-brown during tooth development. You should not use XIMINO during tooth development. Tooth development happens in the second and third trimesters of pregnancy, and from birth to 8 years of age.
- **Slow bone growth**. XIMINO may slow bone growth during second and third trimesters of pregnancy, and from birth to 8 years of age. Slow bone growth is reversible after stopping treatment with XIMINO.
- **Diarrhea.** Diarrhea can happen with most antibiotics, including XIMINO. This diarrhea may be caused by an infection (*Clostridium difficile*) in your intestines. Get medical help right away if you get watery or bloody stools during treatment with XIMINO. You may have stomach cramps and a fever. Diarrhea can happen 2 or more months after you have finished treatment with XIMINO.
- **Liver problems.** XIMINO can cause serious liver problems, including liver failure that may lead to death. Stop taking XIMINO and call your doctor right away if you get any of the following symptoms of liver problems:
  - loss of appetite
  - tiredness
  - diarrhea
  - yellow of your skin or the whites of your eyes
  - unexplained bleeding
  - confusion
  - sleepiness

  Central nervous system effects. See "**What should I avoid while taking XIMINO?**" Central nervous system effects such as light headedness, dizziness, and a spinning feeling (vertigo) may go away during your treatment with XIMINO or if treatment is stopped.
- **Increased pressure around the brain (idiopathic intracranial hypertension).** This condition may lead to vision changes and permanent vision loss. You may be more likely to get intracranial hypertension if you are a female of childbearing potential and are overweight or have a history of intracranial hypertension. Stop taking XIMINO and tell your healthcare provider right away if you develop unusual headache, blurred vision, double vision, or vision loss.
- **Immune system reactions including a lupus-like syndrome, hepatitis, and inflammation of blood or lymph vessels (vasculitis).** Call your healthcare provider right away if you get a fever, rash, joint pain, or body weakness.
- **Discoloration (hyperpigmentation).** XIMINO can cause darkening of your skin, scars, teeth, gums, nails, and whites of your eyes.

The most common side effects of XIMINO include:

- tiredness
- dizziness
- itching

Your healthcare provider may decrease your dose or completely stop treatment with XIMINO if you develop serious side effect.

Your healthcare provider may do blood tests to check you for side effects during treatment with XIMINO.

These are not all of the possible side effects with XIMINO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or Journey Medical Corporation at 1-855-531-1859.

How should I store XIMINO?

- Store XIMINO at room temperature between 68º F to 77º F (20º C to 25º C).
- Keep XIMINO away from light, moisture, and excessive heat.

- Keep XIMINO in the container that it comes in and keep the container tightly closed.

Keep XIMINO and all medicines out of the reach of children.

General information about the safe and effective use of XIMINO.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use XIMINO for a condition for which it was not prescribed. Do not give XIMINO to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about XIMINO that is written for health professionals.

What are the ingredients in XIMINO?

Active ingredient: minocycline hydrochloride.

Inactive ingredients: colloidal silicon dioxide, D&C Yellow #10 (in 45 mg strength), FD&C Blue #1, FD&C Yellow #6 (in 45 mg and 135 mg strength), gelatin, hypromellose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate, and titanium dioxide.

The 45 mg, 90 mg, and 135 mg capsules also contain Opadry Clear which contains hypromellose, polyethylene glycol 400, polyethylene glycol 6000, and talc.

XIMINO extended-release capsules also contain black ink which contains ferrosoferric oxide, potassium hydroxide, propylene glycol, and shellac.

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This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 1/2026