HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SOLODYN safely and effectively. See full prescribing information for SOLODYN.

SOLODYN® (minocycline hydrochloride) extended-release tablets, for oral use
Initial U.S. Approval: 1971

---------- INDICATIONS AND USAGE ----------
SOLODYN 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 SOLODYN only as indicated. (1)

---------- DOSAGE AND ADMINISTRATION ----------
The recommended dosage of SOLODYN is approximately 1 mg/kg once daily for 12 weeks. (2)

---------- DOSAGE FORMS AND STRENGTHS ----------
Extended-release tablets: 55, 65, 80, 105, and 115 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 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). (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 if *Clostridioides difficile*-associated diarrhea (antibiotic-associated colitis) occurs. (5.4)
- *Hepatotoxicity*: Discontinue 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 if symptoms occur. (5.7)
- *Autoimmune Syndromes:* Minocycline has been associated with autoimmune syndromes; discontinue immediately if symptoms occur. (5.8)
- *Metabolic Effects:* If renal impairment exists, reduce SOLODYN dosage. (5.9)

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

To report SUSPECTED ADVERSE REACTIONS, contact Bausch Health US, LLC at 1-800-321-4576 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: 03/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SOLODYN® 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

- SOLODYN 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 SOLODYN only as indicated *[see Warnings and Precautions (5.12)]*.

2 DOSAGE AND ADMINISTRATION

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

Table 1: Dosing Table for SOLODYN

Patient's Weight(kg)	Recommended Dosage (mg/day)
45 – 49	45†
50 – 59	55
60 – 71	65
72 – 84	80
85 – 96	90†
97 – 110	105
111 – 125	115
126 – 136	135

†SOLODYN is not available in the 45 mg and 90 mg strengths; therefore, use an alternative formulation of minocycline hydrochloride extended-release tablets for the 45 mg and 90 mg dosage.

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

Administer SOLODYN extended-release tablets with or without food *[see Clinical Pharmacology (12.3)]*. Ingestion of food along with SOLODYN 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

- 55 mg extended-release tablets: pink, unscored, coated, and debossed with "DYN-055" on one side.
- 65 mg extended-release tablets: blue, unscored, coated, and debossed with "DYN-065" on one side.
- 80 mg extended-release tablets: dark gray, unscored, coated, and debossed with "DYN-080" on one side.

- 105 mg extended-release tablets: purple, unscored, coated, and debossed with "DYN-105" on one side.
- 115 mg extended-release tablets: green, unscored, coated, and debossed with "DYN-115" on one side.

4 CONTRAINDICATIONS

SOLODYN is contraindicated in patients with 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, discontinue SOLODYN immediately.

5.2 Tooth Discoloration and Enamel Hypoplasia

The use of tetracycline-class drugs, including SOLODYN, 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 has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Use of SOLODYN is not recommended during tooth development.

Advise the patient of the potential risk to the fetus if SOLODYN 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 SOLODYN, 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 SOLODYN, 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 SOLODYN 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, discontinue SOLODYN.

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 SOLODYN 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 SOLODYN. These symptoms may disappear during therapy and usually rapidly disappear when SOLODYN is discontinued.

5.7 Idiopathic Intracranial Hypertension

Idiopathic intracranial hypertension has been associated with the use of tetracycline-class drugs, including SOLODYN. 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 SOLODYN 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 SOLODYN.

5.9 Metabolic Effects

The anti-anabolic action of the tetracyclines, including SOLODYN, 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 SOLODYN, and if therapy is prolonged, monitor serum levels SOLODYN.

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 SOLODYN. 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 tetracyclines may develop in patients using SOLODYN. Because of the potential for drug-resistant bacteria to develop during the use of SOLODYN, it should be used only as indicated.

5.13 Superinfection

Use of SOLODYN may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue SOLODYN 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 SOLODYN 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	**SOLODYN (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 SOLODYN 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 SOLODYN 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 this drug, 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 SOLODYN, during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of deciduous 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 times the MRHD 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 dosages 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 breast 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 SOLODYN therapy 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 SOLODYN 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 SOLODYN have not been established in pediatric patients younger than 12 years of age.

8.5 Geriatric Use

Clinical studies of SOLODYN 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.

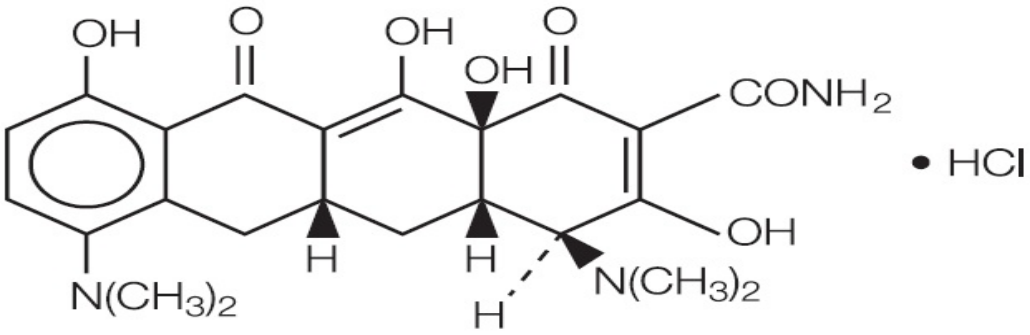
10 OVERDOSAGE

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

11 DESCRIPTION

Minocycline hydrochloride, a semi synthetic derivative of tetracycline, is [4S-(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 monohydrochloride.

The structural formula is represented below:



$C_{23}H_{27}N_3O_7$•HCl M. W. 493.95

SOLODYN extended-release tablets for oral administration contain minocycline hydrochloride USP equivalent to 55 mg, 65 mg, 80 mg, 105 mg, or 115 mg of minocycline. In addition, 55 mg, 65 mg, 80 mg, 105 mg, and 115 mg tablets contain the following inactive ingredients: lactose monohydrate NF, hypromellose type 2910 USP, magnesium stearate NF, colloidal silicon dioxide NF, and carnauba wax NF.

- The 55 mg extended-release tablets also contain Opadry II Pink which contains: hypromellose type 2910 USP, titanium dioxide USP, lactose monohydrate NF, polyethylene glycol 3350 NF, triacetin USP, and FD&C Red #40.

- The 65 mg extended-release tablets also contain Opadry II Blue which contains: hypromellose type 2910 USP, lactose monohydrate NF, FD&C Blue #1, polyethylene glycol 3350 NF, FD&C Blue #2, titanium dioxide USP, triacetin USP, and D&C Yellow #10.
- The 80 mg extended-release tablets also contain Opadry II Gray which contains: hypromellose type 2910 USP, lactose monohydrate NF, polyethylene glycol 3350 NF, FD&C Blue #2, FD&C Red #40, titanium dioxide USP, triacetin USP, and FD&C Yellow #6.
- The 105 mg extended-release tablets also contain Opadry II Purple which contains: hypromellose type 2910 USP, lactose monohydrate NF, titanium dioxide USP, D&C Red #27, polyethylene glycol 3350 NF, triacetin USP, and FD&C Blue #1.
- The 115 mg extended-release tablets also contain Opadry II Green which contains: hypromellose type 2910 USP, lactose monohydrate NF, D&C Yellow #10, triacetin USP, FD&C Blue #1, titanium dioxide USP, and FD&C Blue #2.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of SOLODYN for the treatment of acne is unknown.

12.2 Pharmacodynamics

The pharmacodynamics of SOLODYN for the treatment of acne are unknown.

12.3 Pharmacokinetics

SOLODYN extended-release tablets are not bioequivalent to non-modified release minocycline products. Based on pharmacokinetic studies in healthy adults, SOLODYN extended-release tablets produce a delayed T_{max} at 3.5–4.0 hours as compared to a non-modified release reference minocycline product (T_{max} at 2.25–3 hours). At steady-state (Day 6), the mean $AUC_{(0–24)}$ and C_{max} were 33.32 mcg×hr/mL and 2.63 mcg/mL for SOLODYN extended-release tablets and 46.35 mcg×hr/mL and 2.92 mcg/mL for minocycline hydrochloride capsules, respectively. These parameters are based on dose adjusted to 135 mg/day for both products.

A single-dose, four-way crossover study demonstrated that SOLODYN extended-release tablets used in the study (45 mg, 90 mg, 135 mg) exhibited dose-proportional pharmacokinetics. In another single-dose, five-way crossover pharmacokinetic study, SOLODYN extended-release tablets 55 mg, 80 mg, and 105 mg were shown to be dose-proportional to SOLODYN extended-release tablets 90 mg and 135 mg.

When SOLODYN extended-release tablets were administered concomitantly with a meal that included dairy products, the extent and timing of absorption of minocycline did not differ from that of administration under fasting conditions.

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 HCl was orally administered to male and female rats once daily for up to 104 weeks at dosages up to 200 mg/kg/day, minocycline HCl 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 HCl 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 HCl 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 SOLODYN 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 SOLODYN 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**	
	SOLODYN (1 mg/kg) N = 300	**Placebo N = 151**	**SOLODYN (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

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

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

SOLODYN (minocycline HCl, USP) Extended-Release Tablets are supplied as aqueous film-coated tablets containing minocycline hydrochloride equivalent to 55 mg, 65 mg, 80 mg, 105 mg, or 115 mg minocycline, as follows.

- The 55 mg extended-release tablets are pink, unscored, coated, and debossed with "DYN-055" on one side. Each tablet contains minocycline hydrochloride equivalent to 55 mg minocycline, supplied as follows:

  NDC 99207-465-30 Bottle of 30

- The 65 mg extended-release tablets are blue, unscored, coated, and debossed with "DYN-065" on one side. Each tablet contains minocycline hydrochloride equivalent to 65 mg minocycline, supplied as follows:

  NDC 99207-463-30 Bottle of 30

- The 80 mg extended-release tablets are dark gray, unscored, coated, and debossed with "DYN-080" on one side. Each tablet contains minocycline hydrochloride equivalent to 80 mg minocycline, supplied as follows:

  NDC 99207-466-30 Bottle of 30

- The 105 mg extended-release tablets are purple, unscored, coated, and debossed with "DYN-105" on one side. Each tablet contains minocycline hydrochloride equivalent to 105 mg minocycline, supplied as follows:

  NDC 99207-467-30 Bottle of 30

- The 115 mg extended-release tablets are green, unscored, coated, and debossed with "DYN-115" on one side. Each tablet contains minocycline hydrochloride equivalent to 115 mg minocycline, supplied as follows:

  NDC 99207-464-30 Bottle of 30

Storage

Store at 25°C (77°F); excursions are permitted to 15° to 30°C (59° to 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 SOLODYN extended-release tablets should receive the following information and instructions:

Administration Instructions

- SOLODYN should be taken exactly as directed.
- Advise patients to swallow SOLODYN extended-release tablets whole and not to chew, crush, or split the tablets *[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 SOLODYN 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 SOLODYN use in pregnancy may cause permanent tooth discoloration of deciduous teeth. Advise patients to discontinue SOLODYN 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 SOLODYN 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 SOLODYN use in pregnancy may cause inhibition of fetal bone growth. Advise patients to discontinue SOLODYN 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 SOLODYN. 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, jaundice, 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 SOLODYN *[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 SOLODYN 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 (i.e., tanning beds or UVA/B treatment) while using SOLODYN. Instruct patients to use sunscreen

and wear protective clothing (e.g., hat) over treated areas when exposure to sun cannot be avoided *[see Warnings and Precautions (5.10)]*.

Tissue Hyperpigmentation

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

Lactation

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

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Oakville, Ontario, Canada L6H 1M5

Patented. See https://patents.ortho-dermatologics.com for U.S. patent information.

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PATIENT INFORMATION
SOLODYN® (SO-lo-din)
(minocycline hydrochloride)
extended-release tablets

What is SOLODYN?

SOLODYN is a 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 of age and older.

SOLODYN is not effective for acne that is not red-looking (non-inflammatory acne).

It is not known if SOLODYN is:

- safe and effective for the treatment of infections.
- safe and effective in children under 12 years of age.

Who should not take SOLODYN?

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

Before taking SOLODYN, 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 had increased pressure around your brain that may have caused vision problems
- are pregnant or plan to become pregnant. SOLODYN may harm your unborn baby. Taking SOLODYN while you are pregnant may cause serious side effects on the growth of bone and teeth of your baby. Stop taking SOLODYN and call your healthcare provider right away if you become pregnant during treatment with SOLODYN.
- are breastfeeding or plan to breastfeed. SOLODYN passes into your breast milk and may harm your baby. Do not breastfeed during treatment with SOLODYN and for 4 days after your final dose.

Tell your healthcare provider about all the other medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

SOLODYN and other medicines may affect each other and can cause serious side effects. SOLODYN may affect the way other medicines work, and other medicines may affect how SOLODYN works.

Especially tell your healthcare provider if you take:

- a blood thinner medicine
- a penicillin antibiotic medicine
- antacids that contain aluminum, calcium, or magnesium or iron-containing medicines
- an acne medicine 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.

How should I take SOLODYN?

- Take SOLODYN exactly as your healthcare provider tells you.
- Take SOLODYN 1 time per day with or without food**.** Taking SOLODYN with food may lower your chances of getting irritation or ulcers in your esophagus. Your esophagus is the tube that connects your mouth to your stomach.
- Swallow SOLODYN whole. Do not chew, crush, or split the tablets.

If you take too much SOLODYN, stop taking SOLODYN and call your healthcare provider or go to the nearest hospital emergency room, or contact a poison control center right away at 1-800-222-1222.

What should I avoid while taking SOLODYN?

- You should not drive or operate dangerous machinery until you know how SOLODYN affects you. SOLODYN may cause you to feel dizzy or light-headed or have a spinning feeling (vertigo).
- Avoid sunlight or artificial sunlight, such as sunlamps and tanning beds during treatment with SOLODYN. SOLODYN can make your skin sensitive to the sun and artificial sunlight and you could get severe sunburn during treatment. Use sunscreen and wear a hat and protective clothing that covers your skin while out in the sunlight during treatment with SOLODYN.

What are possible side effects of SOLODYN?

SOLODYN may cause serious side effects, including:

- **Serious skin and allergic reactions** have happened during treatment with minocycline**.** SOLODYN may cause serious skin or allergic reactions that may also affect parts of your body such as your liver, lungs, kidneys, and heart. Sometimes these reactions can lead to death. Stop taking SOLODYN and call your healthcare provider right away or go to the nearest hospital emergency room if you have any of the following signs or symptoms, including:
  - skin redness, 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 (jaundice), 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

- **Permanent tooth discoloration and problems with tooth enamel.** SOLODYN may permanently turn a baby or child's teeth yellow-gray-brown during tooth development. SOLODYN may also cause tooth enamel to not develop properly. You should not use SOLODYN during tooth development. Tooth development happens in the second and third trimesters of pregnancy, and in children from birth to 8 years of age. See "**What should I tell my healthcare provider before taking SOLODYN?**"
- **Slow bone growth.** SOLODYN may cause slow bone growth if it is used during the second and third trimesters of pregnancy and if it is used in infants and children up to 8 years of age. Slow bone growth is reversible after stopping treatment with SOLODYN.
- **Diarrhea (antibiotic associated colitis).** Antibiotic associated colitis can happen with most antibiotics, including SOLODYN. This type of diarrhea may be caused by an infection (Clostridioides difficile) in your intestines and can be severe and can lead to death. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools.
- **Liver problems.** SOLODYN may cause serious liver problems that can lead to death. Stop taking SOLODYN and call your healthcare provider right away if you get any of the following symptoms of liver problems:
  - loss of appetite
  - tiredness
  - diarrhea
  - yellowing of your skin or the whites of your eyes (jaundice)
  - unexplained bleeding or bleeding more easily than normal
  - confusion
  - sleepiness
- **Central nervous system effects.** See "**What should I avoid while taking SOLODYN?**" Central nervous system effects such as light-headedness, dizziness, and a spinning feeling (vertigo) may go away during your treatment with SOLODYN 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 are more likely to get intracranial hypertension if you are a female who can have children, are overweight, and have already had intracranial hypertension. Stop taking SOLODYN and tell your healthcare provider right away if you have blurred vision, double vision, vision loss, or unusual headaches.
- **Immune system reactions including a lupus-like syndrome, hepatitis, and inflammation of blood or lymph vessels (vasculitis).** Using SOLODYN for a long time to treat acne may cause immune system reactions. Stop taking SOLODYN and tell your healthcare provider right away if you get a fever, rash, joint pain, or body weakness.
- **Sensitivity to sunlight (photosensitivity).** See **"What should I avoid while taking SOLODYN?"**
- **Discoloration (tissue hyperpigmentation)**. SOLODYN may cause darkening of your nails, skin, eyes, teeth, gums, scars, and internal organs.

The most common side effects of SOLODYN include:

- headache
- tiredness
- dizziness or spinning feeling
- itching

Your healthcare provider may do blood tests and check you for side effects during treatment with SOLODYN and may lower your dose or stop treatment if you develop certain side effects.

These are not all of the possible side effects of SOLODYN.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Bausch Health US, LLC at 1-800-321-4576.

How should I store SOLODYN?

- Store SOLODYN at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the SOLODYN container tightly closed.
- Keep SOLODYN away from light, moisture, and excessive heat.

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

General information about the safe and effective use of SOLODYN.

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

What are the ingredients in SOLODYN?

Active ingredient: minocycline hydrochloride

Inactive ingredients: lactose monohydrate, hypromellose type 2910, magnesium stearate, colloidal silicon dioxide, and carnauba wax

- 55 mg SOLODYN also contains Opadry II Pink which contains: hypromellose type 2910, titanium dioxide, lactose monohydrate, polyethylene glycol 3350, triacetin, and FD&C Red #40.
- 65 mg SOLODYN also contains Opadry II Blue which contains: hypromellose type 2910, lactose monohydrate, FD&C Blue #1, polyethylene glycol 3350, FD&C Blue #2, titanium dioxide, triacetin, and D&C Yellow #10.
- 80 mg SOLODYN also contains Opadry II Gray which contains: hypromellose type 2910, lactose monohydrate, polyethylene glycol 3350, FD&C Blue #2, FD&C Red #40, titanium dioxide, triacetin, and FD&C Yellow #6.
- 105 mg SOLODYN also contains Opadry II Purple which contains: hypromellose type 2910, lactose monohydrate, titanium dioxide, D&C Red #27, polyethylene glycol 3350, triacetin, and FD&C Blue #1.
- 115 mg SOLODYN also contains Opadry II Green which contains: hypromellose type 2910, lactose monohydrate, D&C Yellow #10, triacetin, FD&C Blue #1, titanium dioxide, and FD&C Blue #2.

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Manufactured by:
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Patented. See https://patents.ortho-dermatologics.com for U.S. patent information.
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For more information, call 1-800-321-4576.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised 03/2025