

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

LAMPRENE® (clofazimine) capsules, for oral use

Initial U.S. Approval: 1986

INDICATIONS AND USAGE

LAMPRENE is an antimycobacterial indicated for the treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum leprosum. (1.1)

To prevent the development of drug-resistance, LAMPRENE should be used only as a part of combination therapy for initial treatment of lepromatous leprosy. (1.2)

DOSAGE AND ADMINISTRATION

- For dapsone-sensitive lepromatous leprosy, 100 mg (two 50 mg capsules) daily with meals as a part of a combination regimen for at least 2 years is recommended. (2.1)
- For dapsone-resistant lepromatous leprosy, 100 mg (two 50 mg capsules) daily with meals in combination with one or more other agents for 3 years. (2.1)
- For lepromatous leprosy complicated by erythema nodosum leprosum, 100 mg (two 50 mg capsules) to 200 mg (four 50 mg capsules) daily for up to 3 months. Taper dose to 100 mg (two 50 mg capsules) as quickly as possible. (2.1)

DOSAGE FORMS AND STRENGTHS

Soft gelatin capsules: 50 mg. (3)

CONTRAINDICATIONS

Known hypersensitivity to clofazimine or to any of the excipients of LAMPRENE. (4)

WARNINGS AND PRECAUTIONS

- Abdominal obstruction and other gastrointestinal adverse reactions: LAMPRENE may deposit in intestinal mucosa causing intestinal

disturbances, including abdominal obstruction, bleeding, splenic infarction and death. Reduce dose or discontinue LAMPRENE if patient complains of pain in abdomen or other gastrointestinal symptoms. (5.1)

- QT prolongation: QT prolongation and Torsade de Pointes may occur with LAMPRENE. Concomitant use with other QT prolonging drugs or bedaquiline may cause additive QT prolongation. Monitor ECGs and discontinue LAMPRENE if significant ventricular arrhythmia or QTcF interval greater than or equal to 500 ms develop. (5.2)
- Skin and body fluid discoloration and other skin reactions: Advise patients that skin and body fluid discoloration frequently occur with use of LAMPRENE. (5.3)
- Depression and suicide due to skin discoloration. Monitor patients for psychological effects of skin discoloration. (5.4)

ADVERSE REACTIONS

Most common adverse reactions reported in 40% to 50% of patients are skin and body fluid discoloration, abdominal and epigastric pain, diarrhea, nausea, vomiting, gastrointestinal intolerance. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Substrates of CYP3A4/5: Monitor for toxicities when used concomitantly with LAMPRENE. (7)

USE IN SPECIFIC POPULATIONS

- Human Immunodeficiency Virus (HIV) Patients: No dose adjustment of LAMPRENE is needed for HIV-infected patients. (8.6)
- Severe Renal Impairment: Use with caution. (8.7)
- Hepatic Impairment: Avoid use. (8.8)

See 17 for PATIENT COUNSELING INFORMATION.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Lepromatous Leprosy

LAMPRENE is indicated in combination with other anti-leprosy drugs for the treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy, and lepromatous leprosy complicated by erythema nodosum leprosum.

1.2 Usage

To prevent the development of drug-resistance, LAMPRENE should be used only as a part of combination therapy for initial treatment of lepromatous (multibacillary) leprosy [*see Dosage and Administration (2.1)*].

For further guidance on the treatment of leprosy, contact the National Hansen's Disease Clinical Center, Baton Rouge, Louisiana (LA) at (1-800-642-2477) or <http://www.hrsa.gov/hansensdisease/clinicalcenter.html>.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

- **Dapsone-sensitive Lepromatous (multibacillary) Leprosy**

Administer 100 mg (two 50 mg capsules) of LAMPRENE daily with meals in combination with two other anti-leprosy drugs for at least 2 years and if possible, until negative skin smears are obtained, followed by monotherapy with an appropriate anti-leprosy drug.

- **Dapsone-resistant Lepromatous Leprosy**

Administer 100 mg (two 50 mg capsules) of LAMPRENE daily with meals in combination with one or more other anti-leprosy drugs for 3 years, followed by monotherapy with 100 mg (two 50 mg capsules) of LAMPRENE daily.

- **Lepromatous Leprosy complicated by Erythema Nodosum Leprosum Reactions**

Administer LAMPRENE at 100 mg (two 50 mg capsules) to 200 mg (four 50 mg capsules) daily, in conjunction with baseline anti-leprosy treatment and steroids as clinically indicated. If LAMPRENE is administered at 200 mg (four 50 mg capsules) dose, taper to 100 mg (two 50 mg capsules) as soon as possible after the erythema nodosum reaction is controlled. Doses of LAMPRENE of more than 100 mg daily should be given for as short a period as possible and only under close medical supervision [*see Warnings and Precautions (5.1)*].

2.2 Important Pre-test Prior to Administration

Sexually-active females of reproductive potential should have a pregnancy test prior to LAMPRENE administration [*see Use in Specific Populations (8.3)*].

3 DOSAGE FORMS AND STRENGTHS

Capsules: 50 mg, brown opaque spherical soft gelatin capsule.

4 CONTRAINDICATIONS

LAMPRENE is contraindicated in patients with known hypersensitivity to clofazimine or any of the excipients of LAMPRENE.

5 WARNINGS AND PRECAUTIONS

5.1 Abdominal Obstruction and Other Gastrointestinal Adverse Reactions

Clofazimine may accumulate in various organs as crystals, including the mesenteric lymph nodes and histiocytes at the lamina propria of the intestinal mucosa, spleen and liver. Deposition in the intestinal mucosa may lead to intestinal obstruction that may necessitate exploratory laparotomy. Splenic infarction, gastrointestinal bleeding, and death have been reported. If a patient complains of pain in the abdomen, nausea, vomiting, or diarrhea, initiate appropriate medical investigations and reduce the daily dose of LAMPRENE, or increase the dosing interval or discontinue the drug. Doses of LAMPRENE of more than 100 mg daily should be given for as short a period as possible (less than 3 months) and only under close medical supervision.

5.2 QT Prolongation

Cases of Torsade de Pointes with QT prolongation have been reported in patients receiving dosage regimens containing higher than 100 mg daily dose of LAMPRENE or in combination with QT prolonging medications. For QT prolongation and Torsade de Pointes cases, the patient must remain under medical surveillance. In all these patients, monitor electrocardiograms (ECGs) for QT prolongation and cardiac rhythm disturbances [*see Dosage and Administration (2.1), Drug Interactions (7.1)*].

QT prolongation has also been reported in patients who were receiving concomitant LAMPRENE and bedaquiline at the recommended dosages. Monitor ECGs in patients taking LAMPRENE and bedaquiline concomitantly, and discontinue LAMPRENE if clinically significant ventricular arrhythmia is noted or if the QTcF interval is 500 ms or greater. If syncope occurs, obtain an ECG to detect QT prolongation.

5.3 Skin and Body Fluid Discoloration and Other Skin Reactions

LAMPRENE causes orange-pink to brownish-black discoloration of the skin, as well as discoloration of the conjunctivae, tears, sweat, sputum, urine and feces in 75%-100% of patients. Advise patients that skin discoloration is likely to occur and that it may take several months or years to reverse after the conclusion of therapy.

Other skin reactions associated with LAMPRENE therapy include ichthyosis, dry skin, and pruritus.

5.4 Psychological Effects of Skin Discoloration

Skin discoloration due to LAMPRENE therapy has been reported to result in depression and suicide. Advise patients regarding skin discoloration and monitor for depression or suicidal ideation during LAMPRENE therapy.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Abdominal Obstruction and Gastrointestinal Adverse Reactions [*see Warnings and Precautions (5.1)*]
- QT Prolongation [*see Warnings and Precautions (5.2)*]
- Skin and Body Fluid Discoloration and Other Skin Reactions [*see Warnings and Precautions (5.3)*]
- Psychological Effects of Skin Discoloration [*see Warnings and Precautions (5.4)*]

The following adverse reactions associated with the use of LAMPRENE were identified. Because these adverse reactions are reported from different studies, these adverse reactions cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse Reactions Occurring In More Than 1% of Patients

Skin: Pigmentation from pink to brownish-black in 75% to 100% of the patients within a few weeks of treatment; ichthyosis and dryness (8% to 28%); rash and pruritus (1% to 5%).

Gastrointestinal: Abdominal and epigastric pain, diarrhea, nausea, vomiting, gastrointestinal intolerance (40% to 50%).

Ocular: Diminished vision, conjunctival and corneal pigmentation due to clofazimine crystal deposits; dryness; burning; itching; irritation.

Other: Discoloration of urine, feces, sputum, sweat; elevated blood sugar; elevated erythrocyte sedimentation rate (ESR).

Adverse Reactions Occurring In Less Than 1% of Patients

Skin: Phototoxicity, erythroderma, acneiform eruptions, monilial cheilosis.

Gastrointestinal: Bowel obstruction, gastrointestinal bleeding, anorexia, constipation, weight loss, hepatitis, jaundice, eosinophilic enteritis, enlarged liver.

Ocular: Maculopathy (bull's eye retinopathy).

Nervous: Dizziness, drowsiness, fatigue, headache, giddiness, neuralgia, taste disorder.

Psychiatric: Depression and suicide secondary to skin discoloration.

Laboratory: Elevated levels of albumin, serum bilirubin, and aspartate aminotransferase (AST); eosinophilia; hypokalemia.

Other: Splenic infarction, thromboembolism, anemia, cystitis, bone pain, edema, fever, lymphadenopathy, vascular pain.

7 DRUG INTERACTIONS

7.1 Effect of LAMPRENE on Substrates of CYP3A

Concomitant use of LAMPRENE may increase concentrations of drugs that are substrates of CYP3A4/5 [see *Clinical Pharmacology (12.3)*] which may increase the risk of toxicity of these drugs. Monitor for toxicities of these drugs when used concomitantly with LAMPRENE.

7.2 Drugs that Prolong QT Interval

QT prolongation and Torsade de Pointes have been reported in patients receiving LAMPRENE in combination with QT prolonging medications, such as bedaquiline. Monitor ECGs for QT prolongation when LAMPRENE is administered with other drugs known to prolong the QT interval [see *Warnings and Precautions (5.2)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data with LAMPRENE use in pregnant women to inform associated risk. Retardation of fetal skull ossification, increased incidences of abortions and stillbirths, and impaired neonatal survival were observed in mice following prenatal exposure to LAMPRENE at 25 mg/kg, equivalent to the 0.6 times maximum recommended human daily dose (200 mg), based on body surface area comparisons. Advise pregnant women of the potential risk to the fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown; however, in the U.S. general population, the estimated background risk of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

The skin of infants born to pregnant mothers who had received LAMPRENE during pregnancy is pigmented at birth.

Limited data is available regarding the reversibility of discoloration. Based on previous observations, discoloration gradually faded over the first year.

Data

Human Data

There are no studies of LAMPRENE use in pregnant women. Few cases of clofazimine use during pregnancy have been reported in the literature. These reports indicate that the skin of infants born to women who had received LAMPRENE during pregnancy was deeply pigmented at birth. LAMPRENE should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Animal Data

Embryo-fetal toxicity studies were conducted in rats, rabbits and mice. In mice, LAMPRENE-induced embryotoxicity and fetotoxicity was evident. Retardation of fetal skull ossification, increased incidences of abortions and stillbirths, and impaired neonatal survival were observed following prenatal exposure to LAMPRENE at 25 mg/kg, equivalent to the 0.6 times maximum recommended human daily dose [MRHD] (200 mg), based on body surface area comparisons. The skin and fatty tissue of offspring became discolored approximately 3 days after birth, which was attributed to the presence of clofazimine in the maternal milk. No developmental effects were observed in rat or rabbits orally administered clofazimine during organogenesis at doses up to 50 mg/kg and 15 mg/kg, (equivalent to about 2.4 and 1.5 times the MRHD of 200 mg based on body surface area) respectively. These animal studies were conducted according to the standards at the time of initial drug approval (1986) and not under current regulatory standards.

8.2 Lactation

Risk Summary

LAMPRENE is excreted in human milk. Skin discoloration has been observed in breast fed neonates of mothers receiving clofazimine.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LAMPRENE and any potential adverse effects on the breastfed infant from LAMPRENE or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Sexually-active females of reproductive potential should have a pregnancy test prior to starting treatment with LAMPRENE.

Contraception

Animal studies have shown LAMPRENE to be harmful to the developing fetus. Advise sexually active females of reproductive potential to use effective contraception (methods that result in less than 1% pregnancy rates) when using LAMPRENE during treatment and for at least 4 months after stopping treatment with LAMPRENE.

Advise males taking LAMPRENE to use a condom during intercourse while on treatment and for at least 4 months after stopping treatment with LAMPRENE.

Infertility

Impaired female fertility (reduced number of offspring and lower proportion of implantations) was observed in one study in rats receiving LAMPRENE [see *Nonclinical Toxicology (13.1)*]. There are no non-clinical data on male fertility.

8.4 Pediatric Use

Safety and effectiveness of LAMPRENE in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of LAMPRENE did not include sufficient numbers of subjects aged 65 and older 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 of concomitant disease or other drug therapy.

8.6 Patients with HIV Co-infection

Response to treatment, including treatment of erythema nodosum leprosum reactions, is not altered in HIV-positive and immunocompromised leprosy patients. Dose adjustments of LAMPRENE are not required in these patients.

8.7 Renal Impairment

No LAMPRENE dosage adjustments are recommended in patients with mild to moderate renal impairment. Use caution in patients with severe renal impairment.

8.8 Hepatic Impairment

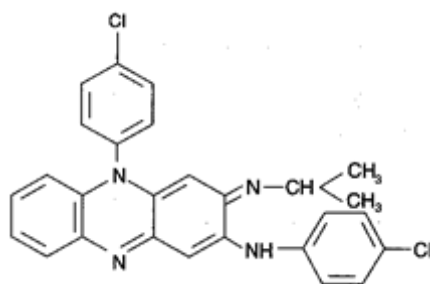
Avoid LAMPRENE in patients with hepatic impairment (Child-Pugh Class A, B, and C) unless the benefit outweighs the risk.

10 OVERDOSAGE

No specific data are available on the treatment of over dosage with LAMPRENE. However, in case of overdose, the stomach should be emptied by inducing vomiting or by gastric lavage, and supportive symptomatic treatment should be employed.

11 DESCRIPTION

LAMPRENE (clofazimine) is an antimycobacterial available as soft gelatin capsules for oral administration. Each capsule contains 50 mg of micronized clofazimine suspended in an oil-wax base. Clofazimine is a substituted iminophenazine bright-red dye. Its chemical name is 3-(p-chloroanilino)-10-(p-chlorophenyl)-2, 10-dihydro-2-isopropyliminophenazine, and its structural formula is



Clofazimine is a reddish-brown powder. It is slightly soluble in acetic acid, dimethylformamide, chloroform and ether; very slightly soluble in ethanol and acetonitrile; soluble in methylene chloride. Its molecular weight is 473.4 g/mol. Its molecular formula is $C_{27}H_{22}Cl_2N_4$.

The Inactive Ingredients

Capsules fill: Anhydrous citric acid, Butylated hydroxytoluene, Fully hydrogenated rapeseed oil, Hydrogenated soybean oil, Lecithin, Partially hydrogenated soybean oil, Propylene glycol, Yellow wax.

Capsule Shells Contain: Ethyl vanillin, Ethylparaben sodium, Gelatin, Glycerol 85%, Iron oxide black slurry with glycerol 85%, Iron oxide red slurry with glycerol 85%, p-methoxy acetophenone, Propylparaben sodium, Purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

LAMPRENE is an anti-mycobacterial drug [see *Microbiology* (12.4)].

12.2 Pharmacodynamics

Clofazimine exposure-response relationships and the time course of pharmacodynamics response are unknown.

12.3 Pharmacokinetics

The average serum concentrations of clofazimine in leprosy patients treated with LAMPRENE 100 mg and 300 mg daily were 0.7 mcg/mL and 1 mcg/mL, respectively.

Absorption

Clofazimine absorption ranges from 45% to 62% in leprosy patients.

Effect of Food

Time to reach peak plasma concentration (median $T_{\max}$) of clofazimine decreases from 12 hours to 8 hours under fed conditions relative to the fasted state.

Distribution

Clofazimine is lipophilic and deposits predominantly in fatty tissue and in cells of the reticuloendothelial system. It is taken up by macrophages throughout the body. In autopsies performed on leprosy patients who had received LAMPRENE, clofazimine crystals were found predominantly in the mesenteric lymph nodes, adrenals, subcutaneous fat, liver, bile, gall bladder, spleen, small intestine, muscles, bones, and skin.

Clofazimine is bound to alpha- and primarily to beta-lipoproteins in serum, and the binding was saturable at plasma concentrations of approximately 10 mcg/mL. Binding to gamma-globulin and albumin was negligible.

Elimination

The mean elimination half-life of clofazimine is approximately 25 days (range 6.5 to 160 days) following repeated oral doses of 50 or 100 mg LAMPRENE in leprosy patients.

Metabolism

Information on the metabolism of clofazimine is limited. Three clofazimine metabolites were found in urine following repeated oral doses of LAMPRENE.

Excretion

After a single dose of LAMPRENE 300 mg, elimination of unchanged clofazimine and its metabolites was negligible in a 24-hour urine collection. Part of the ingested drug recovered from the feces may represent excretion via the bile. A small amount is also eliminated in the sputum, sebum, and sweat.

Drug Interaction Studies

Clinical Studies

No clinically significant differences in clofazimine pharmacokinetics have been observed when used concomitantly with bedaquiline, cycloserine, dapsone, ethionamide, para-aminosalicylic acid, pyrazinamide, and pyridoxine. In patients receiving high doses of clofazimine (300 mg daily) and isoniazid (300 mg daily), elevated concentrations of clofazimine were detected in plasma and urine, although skin concentrations were found to be lower, however the clinical consequences are unknown.

No clinically significant differences in the pharmacokinetics of the following drugs were observed when used concomitantly with clofazimine: dapsone or rifampicin.

In Vitro Studies

Clofazimine inhibits the metabolism of CYP2C8, CYP2D6, CYP3A4/5 drug substrates.

12.4 Microbiology

Mechanism of Action

Clofazimine exerts a slow bactericidal effect on *Mycobacterium leprae* (Hansen's bacillus). Clofazimine inhibits mycobacterial growth and binds preferentially to mycobacterial DNA. Clofazimine also exerts anti-inflammatory properties in treating erythema nodosum leprosum reactions. However, its precise mechanisms of action are unknown.

The mechanism of action for the anti-mycobacterial activity of clofazimine can be postulated through its membrane-directed activity including the bacterial respiratory chain and ion transporters. Intracellular redox cycling, involving oxidation of reduced clofazimine, leads to the generation of antimicrobial reactive oxygen species (ROS), superoxide-hydrogen peroxide (H₂O₂). Secondly, interaction of clofazimine with membrane phospholipids results in the generation of antimicrobial lysophospholipids, which promote membrane dysfunction, resulting in interference with K⁺ uptake. Both mechanisms result in interference with cellular energy metabolism by disrupting ATP production. Anti-inflammatory activity of clofazimine is primarily through inhibition of T lymphocyte activation and proliferation. Clofazimine may indirectly interfere with the proliferation of T cells by promoting the release of ROS and E-series prostaglandins (PGs), especially PGE₂ from neutrophils and monocytes.

Cross-Resistance

Clofazimine does not show cross-resistance with dapsone or rifampin.

Susceptibility Test Methods

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: <https://www.fda.gov/STIC>.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term carcinogenicity studies in animals have not been conducted with LAMPRENE. Results of mutagenicity studies (Ames test) were negative. There is some evidence of clastogenic potential in mice.

Impaired female fertility (reduced number of offspring and lower proportion of implantations) was observed in one study in rats receiving LAMPRENE (from 9 weeks before mating until weaning) at 50 mg/kg/day, equivalent to about 2.4 times the maximum recommended clinical dose (200 mg), based on body surface area comparisons. No non-clinical data on male fertility are available.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Soft Gelatin Capsules 50 mg-brown, opaque, spherical

Bottles of 100.....NDC 0078-1049-05

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature]. Store and dispense in original container. Protect from moisture.

Information for Patients

- Inform patients to take LAMPRENE with meals.
- Inform patients to report abdominal pain or other gastrointestinal symptoms, such as nausea or vomiting, to their healthcare provider.
- Inform patients that LAMPRENE frequently causes a red to brownish-black discoloration of the skin as well as discoloration of the conjunctivae, tears, sweat, sputum, urine, and feces. Advise patients that skin discoloration may take several months or years to resolve after the conclusion of therapy with LAMPRENE.
- Inform patients that skin discoloration may result in psychological effects and advise them to report any symptoms of depression or suicidal ideation.
- Advise females of reproductive potential to use effective contraception while taking LAMPRENE and for at least 4 months after stopping treatment with LAMPRENE. It is also recommended that they have a pregnancy test prior to starting treatment with LAMPRENE.
- Advise males taking LAMPRENE to use a condom during intercourse while taking LAMPRENE and for at least 4 months after stopping treatment.
- Inform patients of the importance of compliance with the prescribed drug regimen in order to prevent drug resistance. Irregularity in administration of medication and poor compliance can lead to delayed and incomplete cure, and could result in infecting other people. Poor compliance can result in disease progression and ultimately result in the development of disabilities and deformities. Whenever possible, ensure that non-compliant patients receive adequate assessment, health education and supervised treatment.
- Instruct patients on the recognition of signs and symptoms of inflammatory reactions and relapses during and following completion of treatment, and instruct them regarding the importance of immediately reporting the earliest manifestations of these signs to their healthcare provider.

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