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Product Name: 30g Oxymetazoline HCl Cream 1% Outsert
Part #: 141382
Folded Size (W x L): 4.0000" x 0.8750"
Flat Size (W x L): 10.0000" x 12.0000"
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Front - Black			
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Rev: 2

Rev.#	Date	BC Grade	Artist
1	09/12/25	A	TA
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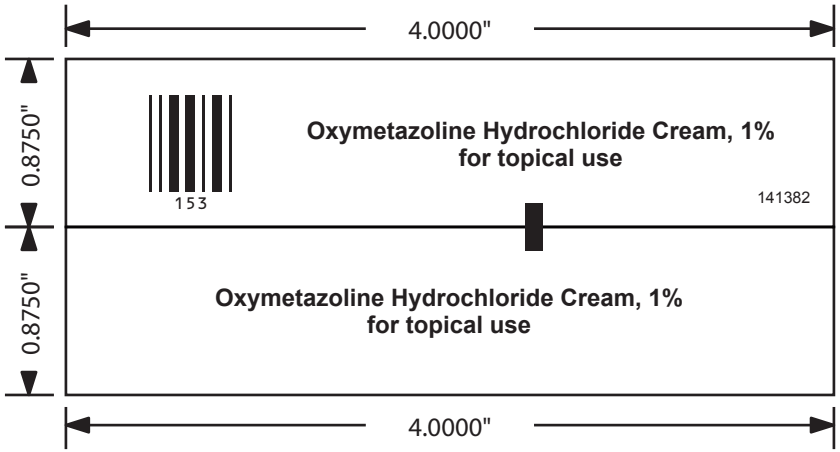

Pharmacode verified @ "153" (rsm 10/13/25)

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DN: dc=com, dc=myl, ou=North America, ou=Texas, ou=Renaissance, ou=_Users, cn=Rosa McKinnon-M112823
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Front

153

Oxymetazoline Hydrochloride Cream, 1% for topical use

141382

Oxymetazoline Hydrochloride Cream, 1% for topical use

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Oxymetazoline Hydrochloride Cream, 1%, for topical use
Initial U.S. Approval: 1964

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

Oxymetazoline Hydrochloride Cream is an alpha$_{1A}$ adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. (1)

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

- Not for oral, ophthalmic, or intravaginal use. (2)
- Prime pump bottle before initial use and discard product from first three pumps. (2)
- Apply a pea-sized amount once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. (2)
- Wash hands after application. (2)

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

Cream, 1%. Each gram of cream contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base. (3)

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

- None. (4)

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

- Alpha-adrenergic agonists as a class may impact blood pressure. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens. (5.1)
- Use with caution in patients with cerebral or coronary insufficiency, Raynaud's phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome and advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop. (5.2)
- Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop. (5.3)

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

Most common adverse reactions (incidence ≥ 1%) are application site dermatitis, worsening inflammatory lesions of rosacea, application site pruritis, application site erythema, and application site pain. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Mayne Pharma at 1-844-825-8500 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

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

141382 Revised: 08/2025

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Oxymetazoline Hydrochloride Cream, 1% is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

2 DOSAGE AND ADMINISTRATION

For topical use only. Oxymetazoline Hydrochloride Cream is not for oral, ophthalmic, or intravaginal use.

Apply a pea-sized amount of Oxymetazoline Hydrochloride Cream, once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. Wash hands immediately after applying Oxymetazoline Hydrochloride Cream.

3 DOSAGE FORMS AND STRENGTHS

Oxymetazoline Hydrochloride Cream, 1% is a white to off-white cream. Each gram of cream contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Potential Impacts on Cardiovascular Disease

Alpha-adrenergic agonists may impact blood pressure. Oxymetazoline Hydrochloride Cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

5.2 Potentiation of Vascular Insufficiency

Oxymetazoline Hydrochloride Cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud's phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

5.3 Risk of Angle Closure Glaucoma

Oxymetazoline Hydrochloride Cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under 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.

A total of 489 subjects with persistent facial erythema associated with rosacea were treated with Oxymetazoline Hydrochloride Cream once daily for 4 weeks in 3 controlled clinical trials. An additional 440 subjects with persistent facial erythema associated with rosacea were also treated with Oxymetazoline Hydrochloride Cream once daily for up to one year in a long-term (open-label) clinical trial. Adverse reactions that occurred in at least 1% of subjects treated with Oxymetazoline Hydrochloride Cream through 4 weeks of treatment are presented in Table 1 below.

Table 1: Adverse Reactions Reported by ≥ 1% of Subjects through 4 Weeks of Treatment in Controlled Clinical Trials

Adverse Reaction	Pooled Controlled Clinical Trials	
	Oxymetazoline HCl Cream (N = 489)	Vehicle Cream (N = 483)
Application site dermatitis	9 (2%)	0
Worsening inflammatory lesions of rosacea	7 (1%)	1 (<1%)
Application site pruritus	5 (1%)	4 (1%)
Application site erythema	5 (1%)	2 (<1%)
Application site pain	4 (1%)	1 (<1%)

In the long-term (open-label) clinical trial, the rates of adverse reactions over a one-year treatment period were as follows: worsening inflammatory lesions of rosacea (3%), application site dermatitis (3%), application site pruritis (2%), application site pain (2%), and application site erythema (2%). Subjects with persistent erythema along with inflammatory lesions were allowed to use additional therapy for the inflammatory lesions of rosacea.

7 DRUG INTERACTIONS

7.1 Anti-hypertensives/Cardiac Glycosides

Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives and/or cardiac glycosides is advised.

Caution should also be exercised in patients receiving alpha$_1$ adrenergic receptor antagonists such as in the treatment of cardiovascular disease, benign prostatic hypertrophy, or Raynaud's disease.

7.2 Monoamine Oxidase Inhibitors

Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Oxymetazoline Hydrochloride Cream use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. A literature article describing intranasal decongestant use in pregnant women identified a potential association between second-trimester exposure to oxymetazoline (with no decongestant exposure in the first trimester) and renal collecting system anomalies *[see Data]*. In animal reproduction studies, there were no adverse developmental effects observed after oral administration of oxymetazoline hydrochloride in pregnant rats and rabbits at systemic exposures up to 3 times and 73 times, respectively, the exposure associated with the maximum recommended human dose (MRHD) *[see Data]*. The estimated background risks of major birth defects and miscarriage for the indicated population are 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 2-4% and 15-20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Following repeated use of oxymetazoline hydrochloride solution nasal spray for the treatment of nasal congestion at a dose 5 times higher than recommended, one case of fetal distress was reported in a 41-week pregnant patient. The fetal distress resolved hours later, prior to the delivery of the healthy infant. The anticipated exposures for the case are 8- to 18-fold higher than plasma exposures after topical administration of Oxymetazoline Hydrochloride Cream.

Data

Human Data

No adequate and well-controlled trials of Oxymetazoline Hydrochloride Cream have been conducted in pregnant women. Across all clinical trials of Oxymetazoline Hydrochloride Cream, two pregnancies were reported. One pregnancy resulted in the delivery of a healthy child. One pregnancy resulted in a spontaneous abortion, which was considered to be unrelated to the trial medication. A literature article summarizing the results of exploratory analyses of intranasal decongestant use during pregnancy identified a potential association between second-trimester exposure to oxymetazoline hydrochloride solution (with no decongestant exposure in the first trimester) and renal collecting system anomalies.

Animal Data

Effects on embryo-fetal development were evaluated in rats and rabbits following oral administration of oxymetazoline hydrochloride during the period of organogenesis. Oxymetazoline hydrochloride did not cause adverse effects to the fetus at oral doses up to 0.2 mg/kg/day in pregnant rats during the period of organogenesis (3 times the MRHD on an AUC comparison basis). Oxymetazoline hydrochloride did not cause adverse effects to the fetus at oral doses up to 1 mg/kg/day in pregnant rabbits during the period of organogenesis (73 times the MRHD on an AUC comparison basis). Maternal toxicity, such as decreased maternal body weight, was produced at the high dose of 1 mg/kg/day in pregnant rabbits and was associated with findings of delayed skeletal ossification.

In a rat perinatal and postnatal development study, oxymetazoline hydrochloride was orally administered to pregnant rats once daily from gestation day 6 through lactation day 20. Maternal toxicity was produced at the high dose of 0.2 mg/kg/day (3 times the MRHD on an AUC comparison basis) in pregnant rats and was associated with an increase in pup mortality and reduced pup body weights. Delayed sexual maturation was noted at 0.1 and 0.2 mg/kg/day (2 times the MRHD and 3 times the MRHD on an AUC comparison basis, respectively). Oxymetazoline hydrochloride did not have any adverse effects on fetal development at a dose of 0.05 mg/kg/day (one-half of the MRHD on an AUC comparison basis).

8.2 Lactation

No clinical data are available to assess the effects of oxymetazoline on the quantity or rate of breastmilk production, or to establish the level of oxymetazoline present in human breastmilk post-dose. Oxymetazoline was detected in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Oxymetazoline Hydrochloride Cream and any potential adverse effects on the breastfed child from Oxymetazoline Hydrochloride Cream or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of Oxymetazoline Hydrochloride Cream have not been established in pediatric patients below the age of 18 years.

8.5 Geriatric Use

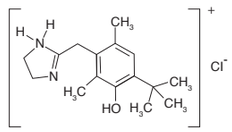
One hundred and ninety-three subjects aged 65 years and older received treatment with Oxymetazoline Hydrochloride Cream (n = 135) or vehicle (n = 58) in clinical trials. No overall differences in safety or effectiveness were observed between subjects ≥ 65 years of age and younger subjects, based on available data. Clinical studies of Oxymetazoline Hydrochloride Cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

10 OVERDOSAGE

Oxymetazoline Hydrochloride Cream is not for oral use. If oral ingestion occurs, seek medical advice. Monitor patient closely and administer appropriate supportive measures as necessary. Accidental ingestion of topical solutions (nasal sprays) containing imidazoline derivatives (e.g., oxymetazoline) in children has resulted in serious adverse events requiring hospitalization, including nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, hypertension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling, and coma. Keep Oxymetazoline Hydrochloride Cream out of reach of children.

11 DESCRIPTION

Oxymetazoline Hydrochloride Cream, 1% contains oxymetazoline hydrochloride, an alpha$_{1A}$ adrenoceptor agonist. Oxymetazoline Hydrochloride Cream is a white to off-white cream. It has a chemical name of 3-[(4,5-Dihydro1H-imidazol-2-yl)methyl]-6-(1,1-dimethylethyl)-2,4-dimethyl-phenol hydrochloride and a molecular weight of 296.8. It is freely soluble in water and ethanol and has a partition coefficient of 0.1 in 1-octanol/water. The molecular formula of oxymetazoline HCl is $C_{16}H_{25}ClN_2O$ and its structural formula is:



Each gram of Oxymetazoline Hydrochloride Cream, 1% contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base. The cream contains the following inactive ingredients: sodium citrate dihydrate, citric acid anhydrous, disodium edetate dihydrate, butylated hydroxytoluene, anhydrous lanolin, medium chain triglycerides, diisopropyl adipate, oleyl alcohol, polyethylene glycol 300, PEG-6 stearate, glycol stearate, PEG-32 stearate, cetostearyl alcohol, ceteareth-6, stearyl alcohol, ceteareth-25, methylparaben, propylparaben, phenoxyethanol, and purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Oxymetazoline is an alpha$_{1A}$ adrenoceptor agonist. Oxymetazoline acts as a vasoconstrictor.

12.2 Pharmacodynamics

The pharmacodynamics of Oxymetazoline Hydrochloride Cream has not been studied.

12.3 Pharmacokinetics

Absorption

The pharmacokinetics of oxymetazoline was evaluated following topical administration of Oxymetazoline Hydrochloride Cream in a thin layer to cover the entire face in adult subjects with erythema associated with rosacea. The median weight of cream for each dose administration was 0.3 g. Plasma oxymetazoline concentrations were measurable in most of the subjects. Following the first dose application, the mean ± standard deviation (SD) peak concentrations (C_{max}) and area under the concentration-time curves from time 0 to 24 hours (AUC_{0-24hr}) were 60.5 ± 53.9 pg/mL and 895 ±798 pg*hr/mL, respectively. Following once daily applications for 28 days, the mean ± SD C_{max} and AUC_{0-24hr} were 66.4 ± 67.1 pg/mL and 1050 ± 992 pg*hr/mL, respectively. Following twice daily applications (twice the recommended frequency of application) for 28 days, the mean ± SD C_{max} and AUC_{0-24hr} were 68.8 ± 61.1 pg/mL and 1530 ± 922 pg*hr/mL, respectively.

Distribution

An *in vitro* study demonstrated that oxymetazoline is 56.7% to 57.5% bound to human plasma proteins.

Metabolism

In vitro studies using human liver microsomes showed that oxymetazoline was minimally metabolized, generating mono-oxygenated and dehydrogenated products of oxymetazoline. The percentage of parent drug oxymetazoline remaining was 95.9% after a 120-minute incubation with human liver microsomes.

Excretion

The excretion of oxymetazoline following administration of Oxymetazoline Hydrochloride Cream has not been characterized in humans.

Drug Interaction

In vitro studies using human liver microsomes demonstrated that oxymetazoline up to the tested concentration of 100 nM had no inhibition on the activities of the cytochrome P450 (CYP) isoenzymes 1A2, 2B6, 2C8, 2C9, 2C19, 2D6, and 3A4/5. Treatment of cultured human hepatocytes with up to 100 nM oxymetazoline did not induce CYP1A2, CYP2B6, or CYP3A4.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Oxymetazoline hydrochloride was not associated with an increased incidence of neoplastic or proliferative changes in transgenic mice given oral doses of 0.5, 1.0, or 2.5 mg/kg/day oxymetazoline hydrochloride for 6 months.

Oxymetazoline hydrochloride revealed no evidence of mutagenic or clastogenic potential based on the results of two *in vitro* genotoxicity tests (Ames assay and human lymphocyte chromosomal aberration assay) and one *in vivo* genotoxicity test (mouse micronucleus assay).

Effects on fertility and early embryonic development were evaluated in rats following oral administration of 0.05, 0.1, or 0.2 mg/kg/day oxymetazoline hydrochloride prior to and during mating and through early pregnancy. Decreased number of corpora lutea and increased post-implantation losses were noted at 0.2 mg/kg/day oxymetazoline hydrochloride (3 times the MRHD on an AUC comparison basis). However, no treatment related effects on fertility or mating parameters were noted at 0.2 mg/kg/day oxymetazoline hydrochloride (3 times the MRHD on an AUC comparison basis).

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14 CLINICAL STUDIES

Oxymetazoline Hydrochloride Cream was evaluated for the treatment of persistent erythema associated with rosacea in two identical, randomized, double-blind, vehicle-controlled, parallel-group clinical trials. The trials enrolled 885 subjects aged 18 years and older. Overall, 90% of subjects were Caucasian and 79% were female. Subjects applied either Oxymetazoline Hydrochloride Cream or vehicle once daily for 29 days.

Disease severity was graded by the clinician using a 5-point clinician erythema assessment (CEA) scale and by the subject on a similar 5-point subject self-assessment (SSA) scale, on which subjects scored either “moderate” or “severe” on both scales.

CEA and SSA were measured over a 12-hour period at equally-spaced timepoints (hours 3, 6, 9, and 12) post dose on Days 1, 15, and 29. The primary efficacy endpoint was defined as the proportion of subjects with at least a 2-grade reduction in erythema (improvement) from baseline (pre-dose on Day 1) on both the CEA and SSA measured at hours 3, 6, 9, and 12 on Day 29. The results from both trials on the composite endpoint for Day 29 are presented in Table 2.

Table 2: Proportion of Subjects Achieving Composite Success* on Day 29

Time-point (Hour)	Trial 1		Trial 2	
	Oxymetazoline HCl Cream (N=222)	Vehicle Cream (N=218)	Oxymetazoline HCl Cream (N = 224)	Vehicle Cream (N=221)
3	12%	6%	14%	7%
6	16%	8%	13%	5%
9	18%	6%	16%	9%
12	15%	6%	12%	6%

*Composite success is defined as the proportion of subjects achieving at least a 2-grade improvement on both CEA and SSA.

16 HOW SUPPLIED/STORAGE AND HANDLING

Oxymetazoline Hydrochloride Cream,1% is a white to off-white cream. The product is available in a laminated tube in the following packaging configuration each with a child-resistant closure:

NDC 68308-**766**-30 30 gram tube

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

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (*Patient Information* and *Instructions for Use*).

Important Administration Instructions
Advise patients of the following:

- Oxymetazoline Hydrochloride Cream is for topical use only.
- Do not apply Oxymetazoline Hydrochloride Cream to irritated skin or open wounds.
- Avoid contact with the eyes and lips.
- Wash hands immediately after application.
- Keep Oxymetazoline Hydrochloride Cream out of reach of children.

Distributed by:
Mayne Pharma
Raleigh, NC 27609

Patented. U.S. Patent Numbers: U.S. 7,812,049; U.S. 8,420,688; U.S. 8,815,929; U.S. 8,883,838; U.S. 9,974,773 and U.S. 10335391. Product of Germany

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PATIENT INFORMATION
Oxymetazoline Hydrochloride Cream, 1%

Important: Oxymetazoline Hydrochloride Cream is for skin (topical) use on the face only. Do not use Oxymetazoline Hydrochloride Cream in your eyes, mouth, or vagina.

Keep Oxymetazoline Hydrochloride Cream out of the reach of children.
Get medical help right away if you, a child, or anyone else swallows Oxymetazoline Hydrochloride Cream.

What is Oxymetazoline Hydrochloride Cream?

Oxymetazoline Hydrochloride Cream is a prescription medicine used on the skin (topical) to treat facial redness due to rosacea that does not go away (persistent) in adults.

It is not known if Oxymetazoline Hydrochloride Cream is safe and effective in children under 18 years of age.

Before you use Oxymetazoline Hydrochloride Cream, tell your healthcare provider about all of your medical conditions, including if you:

- have heart, blood vessel, or blood pressure problems. Call your healthcare provider or get medical help if these conditions worsen.
- have problems with blood circulation or have had a stroke
- have Sjögren’s Syndrome
- have scleroderma
- have Raynaud’s phenomenon
- have thromboangiitis obliterans
- have narrow-angle glaucoma. Call your healthcare provider or get medical help if your glaucoma worsens.
- have irritated skin or open sores on the face
- are pregnant or plan to become pregnant. It is not known if Oxymetazoline Hydrochloride Cream will harm your unborn baby.
- are breastfeeding. It is not known if Oxymetazoline Hydrochloride Cream passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use Oxymetazoline Hydrochloride Cream.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, skin products, vitamins, and herbal supplements. Using Oxymetazoline Hydrochloride Cream with certain other medicines may affect each other and can cause serious side effects.

How should I use Oxymetazoline Hydrochloride Cream?

- See the detailed Instructions for Use that comes with your Oxymetazoline Hydrochloride Cream tube for information about how to apply Oxymetazoline Hydrochloride Cream correctly.
- Use Oxymetazoline Hydrochloride Cream exactly as your healthcare provider tells you. Do not use more Oxymetazoline Hydrochloride Cream than prescribed.
- Oxymetazoline Hydrochloride Cream is for use on your skin only. **Do not** use Oxymetazoline Hydrochloride Cream in your eyes, mouth, or vagina. Avoid contact with your lips and eyes.
- **Do not** apply Oxymetazoline Hydrochloride Cream to irritated skin or open wounds.

What are the possible side effects of Oxymetazoline Hydrochloride Cream?

The most common side effects of Oxymetazoline Hydrochloride Cream include application site reactions of:

- skin reactions (dermatitis)
- worsening of rosacea pimples
- itching
- redness
- pain

These are not all the possible side effects of Oxymetazoline Hydrochloride Cream.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Oxymetazoline Hydrochloride Cream?

- Store Oxymetazoline Hydrochloride Cream at room temperature between 68°F to 77°F (20°C to 25°C).

Keep Oxymetazoline Hydrochloride Cream and all medicines out of the reach of children.

General information about the safe and effective use of Oxymetazoline Hydrochloride Cream

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

What are the ingredients in Oxymetazoline Hydrochloride Cream?

Active ingredient: oxymetazoline hydrochloride

Inactive ingredients: sodium citrate dihydrate, citric acid anhydrous, disodium edetate dihydrate, butylated hydroxytoluene, anhydrous lanolin, medium chain triglycerides, diisopropyl adipate, oleyl alcohol, polyethylene glycol 300, PEG-6 stearate, glycol stearate, PEG-32 stearate, cetostearyl alcohol, ceteareth-6, stearyl alcohol, ceteareth-25, methylparaben, propylparaben, phenoxyethanol, and purified water

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Patented. U.S. Patent Numbers: U.S. 7,812,049; U.S. 8,420,688; U.S. 8,815,929; U.S. 8,883,838; U.S. 9,974,773 and U.S. 10335391. Product of Germany

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This Patient Information has been approved by the U.S. Food and Drug Administration
Revised: 08/2025

INSTRUCTIONS FOR USE
Oxymetazoline Hydrochloride Cream, 1%

Important:

- Oxymetazoline Hydrochloride Cream is for skin (topical) use on the face only. Do not use Oxymetazoline Hydrochloride Cream in your eyes, mouth, or vagina.
- **Keep Oxymetazoline Hydrochloride Cream out of the reach of children.**
- **Get medical help right away if you, a child, or anyone else swallows Oxymetazoline Hydrochloride Cream.**

Read and follow the steps below so that you use your tube of Oxymetazoline Hydrochloride Cream correctly:

Step 1: Open the tube of Oxymetazoline Hydrochloride Cream by gently pressing **down** on the child-resistant cap and twisting it **counterclockwise** until the cap is removed. Do not squeeze the tube while opening or closing.

Note: When the cap is removed, the tube is not child-resistant.

Step 2: To apply Oxymetazoline Hydrochloride Cream to your face, squeeze a pea-sized amount of Oxymetazoline Hydrochloride Cream from the tube onto your fingertip.

Step 3: Apply the pea-sized amount of Oxymetazoline Hydrochloride Cream to cover your entire face (forehead, nose, each cheek, and chin) 1 time each day. Spread the cream smoothly and evenly in a thin layer over your face.

- Avoid contact with your eyes and lips.
- **Do not** apply cream to irritated skin or open wounds.

Step 4: To close your Oxymetazoline Hydrochloride Cream tube, place the cap back on the tube. Press down on the child-resistant cap and twist clockwise until it stops. The tube is child-resistant again.

Step 5: Wash your hands right away after applying Oxymetazoline Hydrochloride Cream.

How do I store Oxymetazoline Hydrochloride Cream?

- Store Oxymetazoline Hydrochloride Cream at room temperature between 68°F to 77°F (20°C to 25°C).

Keep Oxymetazoline Hydrochloride Cream and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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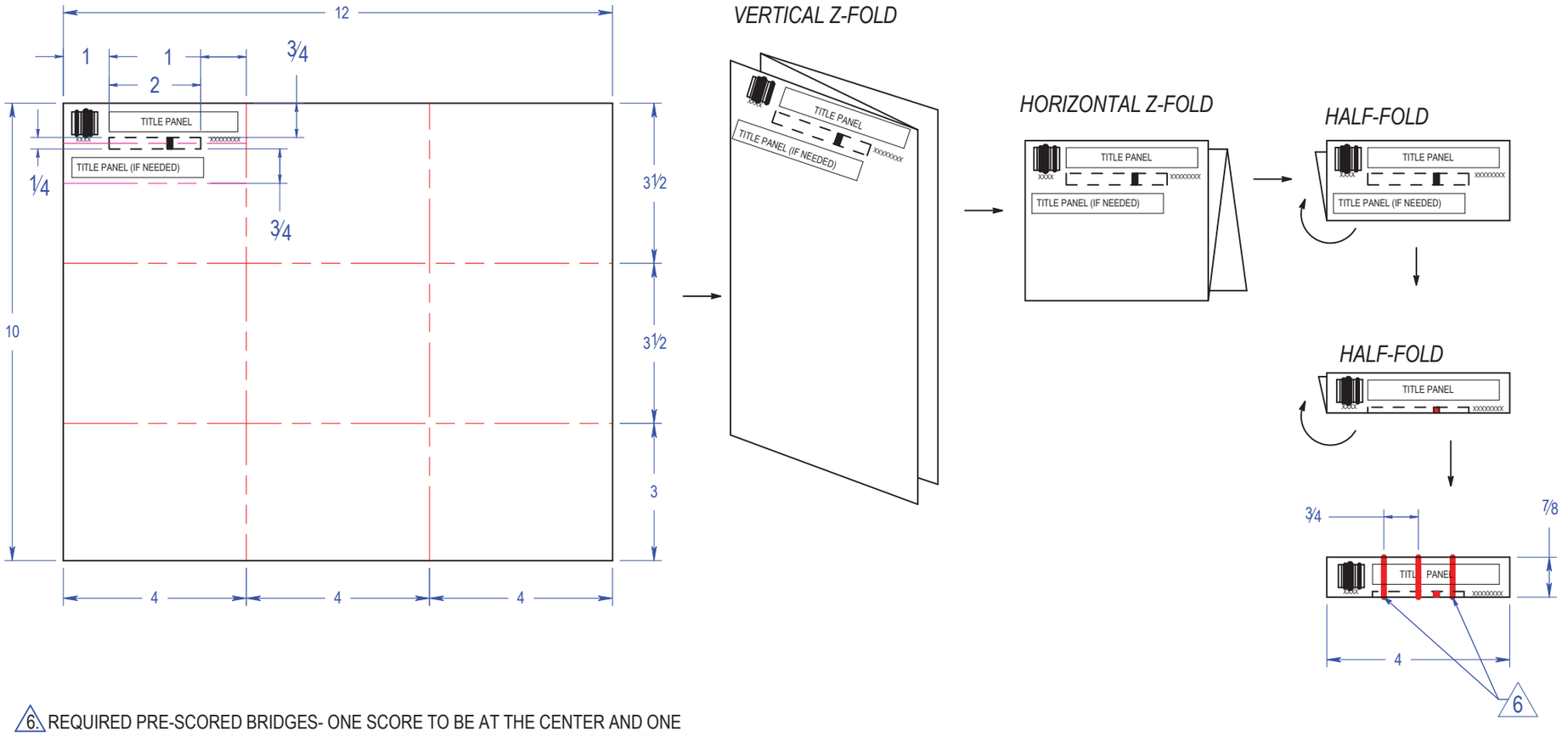
Rev. 2

Fold Pattern



6. REQUIRED PRE-SCORED BRIDGES- ONE SCORE TO BE AT THE CENTER AND ONE SCORE ON EACH SIDE SEPARATED BY 3/4". SCORE TO BE APPLIED TO THE FAT SIDE OF THE FOLDED INSERT.

5. ALL DIMENSIONS ARE IN INCHES.

4. SIZE: 12" X 10" FLAT (±1/32"), FOLDED TO 4" X 7/8" (±1/16")

3. COLOR: WHITE

2. MATERIAL: 27- 30 LB. STOCK PAPER

1. STYLE: Z-FOLD, RIGHT-ANGLE FOLD INSERT

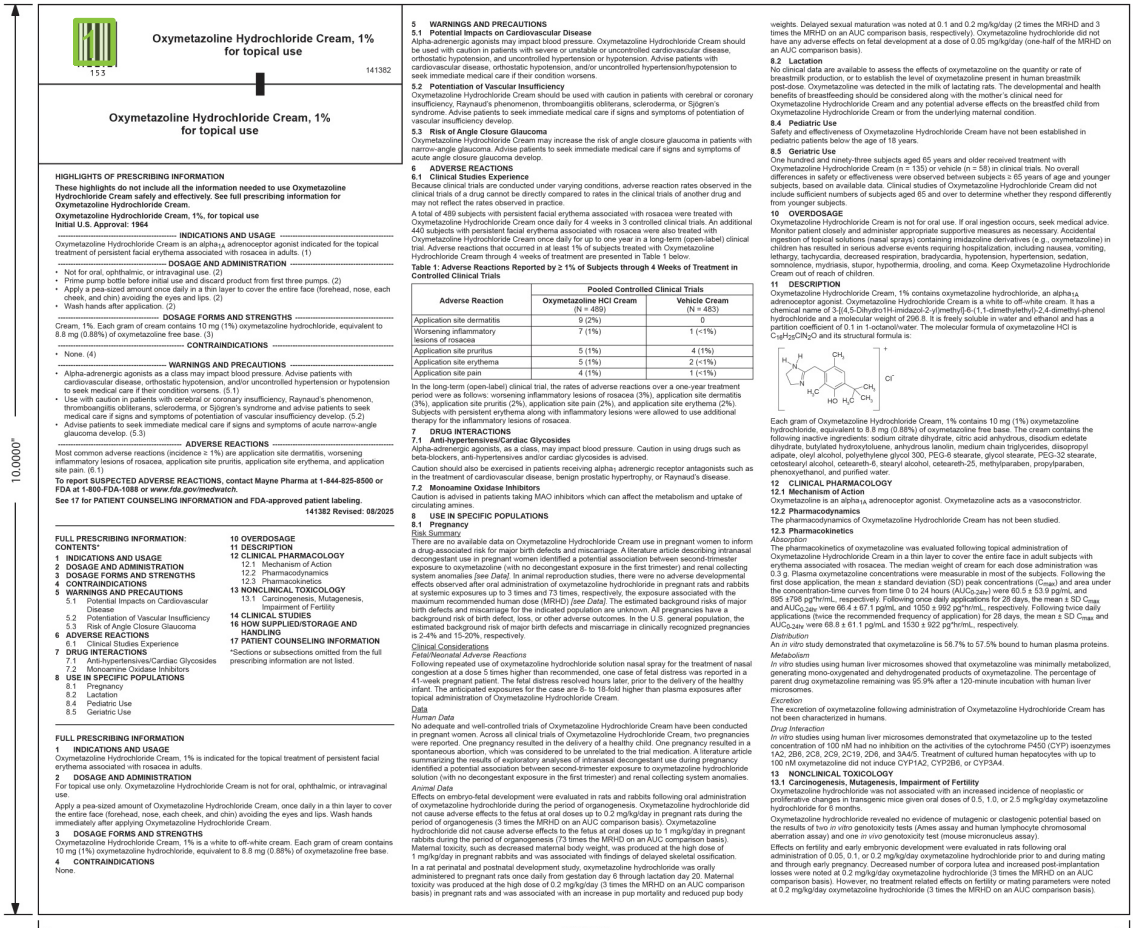
GENERAL NOTES: UNLESS OTHERWISE SPECIFIED

Rev: 2

File: ...ne HCl Cream 1pct Outsert (141382) Rev. 2.pdf
Inspection: 2 Barcode Inspect Master
Inspected by: graphics
Inspected on: 10/8/2025 1:52 PM (UTC-5:00)

Status: Pass
Product ID:
Product Lot #:
Product Name:

Front



153

141382

Oxymetazoline Hydrochloride Cream, 1% for topical use

Oxymetazoline Hydrochloride Cream, 1% for topical use

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Oxymetazoline Hydrochloride Cream, 1%, for topical use
Initial U.S. Approval: 1964

INDICATIONS AND USAGE

Oxymetazoline Hydrochloride Cream is an alpha$_{1A}$ adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. (1)

DOSAGE AND ADMINISTRATION

- Not for oral, ophthalmic, or intravaginal use. (2)
- Prime pump bottle before initial use and discard product from first three pumps. (2)
- Apply a pea-sized amount once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. (2)
- Wash hands after application. (2)

DOSAGE FORMS AND STRENGTHS

Cream, 1%. Each gram of cream contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base. (3)

CONTRAINDICATIONS

- None. (4)

WARNINGS AND PRECAUTIONS

- Alpha-adrenergic agonists as a class may impact blood pressure. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens. (5.1)
- Use with caution in patients with cerebral or coronary insufficiency, Raynaud's phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome and advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop. (5.2)
- Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop. (5.3)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 1%) are application site dermatitis, worsening inflammatory lesions of rosacea, application site pruritis, application site erythema, and application site pain. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Mayne Pharma at 1-844-825-8500 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

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

141382 Revised: 08/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Potential Impacts on Cardiovascular Disease
5.2 Potentiation of Vascular Insufficiency
5.3 Risk of Angle Closure Glaucoma
6 ADVERSE REACTIONS
6.1 Clinical Studies Experience
7 DRUG INTERACTIONS
7.1 Anti-hypertensives/Cardiac Glycosides
7.2 Monoamine Oxidase Inhibitors
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
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16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Oxymetazoline Hydrochloride Cream, 1% is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

2 DOSAGE AND ADMINISTRATION

For topical use only. Oxymetazoline Hydrochloride Cream is not for oral, ophthalmic, or intravaginal use.

Apply a pea-sized amount of Oxymetazoline Hydrochloride Cream, once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. Wash hands immediately after applying Oxymetazoline Hydrochloride Cream.

3 DOSAGE FORMS AND STRENGTHS

Oxymetazoline Hydrochloride Cream, 1% is a white to off-white cream. Each gram of cream contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Potential Impacts on Cardiovascular Disease

Alpha-adrenergic agonists may impact blood pressure. Oxymetazoline Hydrochloride Cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

5.2 Potentiation of Vascular Insufficiency

Oxymetazoline Hydrochloride Cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud's phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

5.3 Risk of Angle Closure Glaucoma

Oxymetazoline Hydrochloride Cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under 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.

A total of 489 subjects with persistent facial erythema associated with rosacea were treated with Oxymetazoline Hydrochloride Cream once daily for 4 weeks in 3 controlled clinical trials. An additional 440 subjects with persistent facial erythema associated with rosacea were also treated with Oxymetazoline Hydrochloride Cream once daily for up to one year in a long-term (open-label) clinical trial. Adverse reactions that occurred in at least 1% of subjects treated with Oxymetazoline Hydrochloride Cream through 4 weeks of treatment are presented in Table 1 below.

Table 1: Adverse Reactions Reported by ≥ 1% of Subjects through 4 Weeks of Treatment in Controlled Clinical Trials

Adverse Reaction	Pooled Controlled Clinical Trials	
	Oxymetazoline HCl Cream (N = 489)	Vehicle Cream (N = 483)
Application site dermatitis	9 (2%)	0
Worsening inflammatory lesions of rosacea	7 (1%)	1 (<1%)
Application site pruritus	5 (1%)	4 (1%)
Application site erythema	5 (1%)	2 (<1%)
Application site pain	4 (1%)	1 (<1%)

In the long-term (open-label) clinical trial, the rates of adverse reactions over a one-year treatment period were as follows: worsening inflammatory lesions of rosacea (3%), application site dermatitis (3%), application site pruritis (2%), application site pain (2%), and application site erythema (2%). Subjects with persistent erythema along with inflammatory lesions were allowed to use additional therapy for the inflammatory lesions of rosacea.

7 DRUG INTERACTIONS

7.1 Anti-hypertensives/Cardiac Glycosides

Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives and/or cardiac glycosides is advised.

Caution should also be exercised in patients receiving alpha$_1$ adrenergic receptor antagonists such as in the treatment of cardiovascular disease, benign prostatic hypertrophy, or Raynaud's disease.

7.2 Monoamine Oxidase Inhibitors

Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Oxymetazoline Hydrochloride Cream use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. A literature article describing intranasal decongestant use in pregnant women identified a potential association between second-trimester exposure to oxymetazoline (with no decongestant exposure in the first trimester) and renal collecting system anomalies *[see Data]*. In animal reproduction studies, there were no adverse developmental effects observed after oral administration of oxymetazoline hydrochloride in pregnant rats and rabbits at systemic exposures up to 3 times and 73 times, respectively, the exposure associated with the maximum recommended human dose (MRHD) *[see Data]*. The estimated background risks of major birth defects and miscarriage for the indicated population are 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 2-4% and 15-20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Following repeated use of oxymetazoline hydrochloride solution nasal spray for the treatment of nasal congestion at a dose 5 times higher than recommended, one case of fetal distress was reported in a 41-week pregnant patient. The fetal distress resolved hours later, prior to the delivery of the healthy infant. The anticipated exposures for the case are 8- to 18-fold higher than plasma exposures after topical administration of Oxymetazoline Hydrochloride Cream.

Data

Human Data

No adequate and well-controlled trials of Oxymetazoline Hydrochloride Cream have been conducted in pregnant women. Across all clinical trials of Oxymetazoline Hydrochloride Cream, two pregnancies were reported. One pregnancy resulted in the delivery of a healthy child. One pregnancy resulted in a spontaneous abortion, which was considered to be unrelated to the trial medication. A literature article summarizing the results of exploratory analyses of intranasal decongestant use during pregnancy identified a potential association between second-trimester exposure to oxymetazoline hydrochloride solution (with no decongestant exposure in the first trimester) and renal collecting system anomalies.

Animal Data

Effects on embryo-fetal development were evaluated in rats and rabbits following oral administration of oxymetazoline hydrochloride during the period of organogenesis. Oxymetazoline hydrochloride did not cause adverse effects to the fetus at oral doses up to 0.2 mg/kg/day in pregnant rats during the period of organogenesis (3 times the MRHD on an AUC comparison basis). Oxymetazoline hydrochloride did not cause adverse effects to the fetus at oral doses up to 1 mg/kg/day in pregnant rabbits during the period of organogenesis (73 times the MRHD on an AUC comparison basis). Maternal toxicity, such as decreased maternal body weight, was produced at the high dose of 1 mg/kg/day in pregnant rabbits and was associated with findings of delayed skeletal ossification.

In a rat perinatal and postnatal development study, oxymetazoline hydrochloride was orally administered to pregnant rats once daily from gestation day 6 through lactation day 20. Maternal toxicity was produced at the high dose of 0.2 mg/kg/day (3 times the MRHD on an AUC comparison basis) in pregnant rats and was associated with an increase in pup mortality and reduced pup body weights. Delayed sexual maturation was noted at 0.1 and 0.2 mg/kg/day (2 times the MRHD and 3 times the MRHD on an AUC comparison basis, respectively). Oxymetazoline hydrochloride did not have any adverse effects on fetal development at a dose of 0.05 mg/kg/day (one-half of the MRHD on an AUC comparison basis).

8.2 Lactation

No clinical data are available to assess the effects of oxymetazoline on the quantity or rate of breastmilk production, or to establish the level of oxymetazoline present in human breastmilk post-dose. Oxymetazoline was detected in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Oxymetazoline Hydrochloride Cream and any potential adverse effects on the breastfed child from Oxymetazoline Hydrochloride Cream or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of Oxymetazoline Hydrochloride Cream have not been established in pediatric patients below the age of 18 years.

8.5 Geriatric Use

One hundred and ninety-three subjects aged 65 years and older received treatment with Oxymetazoline Hydrochloride Cream (n = 135) or vehicle (n = 58) in clinical trials. No overall differences in safety or effectiveness were observed between subjects ≥ 65 years of age and younger subjects, based on available data. Clinical studies of Oxymetazoline Hydrochloride Cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

10 OVERDOSAGE

Oxymetazoline Hydrochloride Cream is not for oral use. If oral ingestion occurs, seek medical advice. Monitor patient closely and administer appropriate supportive measures as necessary. Accidental ingestion of topical solutions (nasal sprays) containing imidazoline derivatives (e.g., oxymetazoline) in children has resulted in serious adverse events requiring hospitalization, including nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, hypertension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling, and coma. Keep Oxymetazoline Hydrochloride Cream out of reach of children.

11 DESCRIPTION

Oxymetazoline Hydrochloride Cream, 1% contains oxymetazoline hydrochloride, an alpha$_{1A}$ adrenoceptor agonist. Oxymetazoline Hydrochloride Cream is a white to off-white cream. It has a chemical name of 3-[(4,5-Dihydro1H-imidazol-2-yl)methyl]-6-(1,1-dimethylethyl)-2,4-dimethyl-phenol hydrochloride and a molecular weight of 296.8. It is freely soluble in water and ethanol and has a partition coefficient of 0.1 in 1-octanol/water. The molecular formula of oxymetazoline HCl is $C_{16}H_{25}ClN_2O$ and its structural formula is:

Each gram of Oxymetazoline Hydrochloride Cream, 1% contains 10 mg (1%) oxymetazoline hydrochloride, equivalent to 8.8 mg (0.88%) of oxymetazoline free base. The cream contains the following inactive ingredients: sodium citrate dihydrate, citric acid anhydrous, disodium edetate dihydrate, butylated hydroxytoluene, anhydrous lanolin, medium chain triglycerides, diisopropyl adipate, oleyl alcohol, polyethylene glycol 300, PEG-6 stearate, glycol stearate, PEG-32 stearate, cetostearyl alcohol, ceteareth-6, stearyl alcohol, ceteareth-25, methylparaben, propylparaben, phenoxyethanol, and purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Oxymetazoline is an alpha$_{1A}$ adrenoceptor agonist. Oxymetazoline acts as a vasoconstrictor.

12.2 Pharmacodynamics

The pharmacodynamics of Oxymetazoline Hydrochloride Cream has not been studied.

12.3 Pharmacokinetics

Absorption

The pharmacokinetics of oxymetazoline was evaluated following topical administration of Oxymetazoline Hydrochloride Cream in a thin layer to cover the entire face in adult subjects with erythema associated with rosacea. The median weight of cream for each dose administration was 0.3 g. Plasma oxymetazoline concentrations were measurable in most of the subjects. Following the first dose application, the mean ± standard deviation (SD) peak concentrations (C_{max}) and area under the concentration-time curves from time 0 to 24 hours (AUC_{0-24hr}) were 60.5 ± 53.9 pg/mL and 895 ± 796 pg*hr/mL, respectively. Following once daily applications for 28 days, the mean ± SD C_{max} and AUC_{0-24hr} were 66.4 ± 67.1 pg/mL and 1050 ± 992 pg*hr/mL, respectively. Following twice daily applications (twice the recommended frequency of application) for 28 days, the mean ± SD C_{max} and AUC_{0-24hr} were 68.8 ± 61.1 pg/mL and 1530 ± 922 pg*hr/mL, respectively.

Distribution

An *in vitro* study demonstrated that oxymetazoline is 56.7% to 57.5% bound to human plasma proteins.

Metabolism

In vitro studies using human liver microsomes showed that oxymetazoline was minimally metabolized, generating mono-oxygenated and dehydrogenated products of oxymetazoline. The percentage of parent drug oxymetazoline remaining was 95.9% after a 120-minute incubation with human liver microsomes.

Excretion

The excretion of oxymetazoline following administration of Oxymetazoline Hydrochloride Cream has not been characterized in humans.

Drug Interaction

In vitro studies using human liver microsomes demonstrated that oxymetazoline up to the tested concentration of 100 nM had no inhibition on the activities of the cytochrome P450 (CYP) isoenzymes 1A2, 2B6, 2C8, 2C9, 2C19, 2D6, and 3A4/5. Treatment of cultured human hepatocytes with up to 100 nM oxymetazoline did not induce CYP1A2, CYP2B6, or CYP3A4.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Oxymetazoline hydrochloride was not associated with an increased incidence of neoplastic or proliferative changes in transgenic mice given oral doses of 0.5, 1.0, or 2.5 mg/kg/day oxymetazoline hydrochloride for 6 months.

Oxymetazoline hydrochloride revealed no evidence of mutagenic or clastogenic potential based on the results of two *in vitro* genotoxicity tests (Ames assay and human lymphocyte chromosomal aberration assay) and one *in vivo* genotoxicity test (mouse micronucleus assay).

Effects on fertility and early embryonic development were evaluated in rats following oral administration of 0.05, 0.1, or 0.2 mg/kg/day oxymetazoline hydrochloride prior to and during mating and through early pregnancy. Decreased number of corpora lutea and increased post-implantation losses were noted at 0.2 mg/kg/day oxymetazoline hydrochloride (3 times the MRHD on an AUC comparison basis). However, no treatment related effects on fertility or mating parameters were noted at 0.2 mg/kg/day oxymetazoline hydrochloride (3 times the MRHD on an AUC comparison basis).

10.0000"

12.0000"

Front Bottom Right Corner

Rev. 2

Barcode Results Summary	Grade A	Grade B	Grade C	Grade D	Grade F	N/A
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GVD | Barcode Inspection Report

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Inspection: 2 Barcode Inspect Master
Inspected by: graphics
Inspected on: 10/8/2025 1:52 PM (UTC-5:00)

Status: Pass
Product ID:
Product Lot #:
Product Name:

Barcode ID:	1	Grade:	A
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Wide To Narrow Ratio:	N/A	Data Structure:	N/A
Wide Bar:	F (1.29 mm)	Gap:	A (0.91 mm)

Decoded value: Left/Bottom: 153 Right/Top: 171

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Inspection: 2 Barcode Inspect Master
Inspected by: graphics
Inspected on: 10/8/2025 1:52 PM (UTC-5:00)

Status: Pass
Product ID:
Product Lot #:
Product Name:

Inspection Parameters (Technical)

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Median filter: None
Open filter: None
Close filter: None
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Grade Output format: Letters

Linear

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ISO/IEC 15416:2016: Off
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Support Negative Barcodes: Off
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Include in Grading: Narrow Bar Off
Include in Grading: Wide To Narrow Ratio Off
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Nominal Measurements for USPS 4-State: On

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Codabar: On
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USPS 4-State: On

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QR

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Inspection: 2 Barcode Inspect Master	Product ID:
Inspected by: graphics	Product Lot #:
Inspected on: 10/8/2025 1:52 PM (UTC-5:00)	Product Name:

Comments

Performed By: Todd Allen

Reviewed By: _____