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

LOCOID LIPOCREAM® (hydrocortisone butyrate) cream, for topical use

Initial U.S. Approval: 1982

---------- RECENT MAJOR CHANGES ----------
Warnings and Precautions (5.1, 5.2) 7/2024

---------- INDICATIONS AND USAGE ----------
Locoid Lipocream® is a corticosteroid indicated for:
- Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults. (1)
- The topical treatment of mild to moderate atopic dermatitis in pediatric patients 3 months of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
- Corticosteroid-Responsive Dermatoses: Apply a thin layer to the affected skin areas 2 or 3 times daily for corticosteroid-responsive dermatoses in adults. Rub in gently. (2)
- Atopic Dermatitis: Apply a thin layer to the affected skin areas 2 times daily for atopic dermatitis in pediatric patients 3 months of age and older. Rub in gently. (2)
- Discontinue Locoid Lipocream when control is achieved. (2)
- Reassess diagnosis if no improvement is seen within 2 weeks. Before prescribing for more than 2 weeks, weigh any additional benefits of extending treatment up to 4 weeks against the risk of hypothalamic-pituitary-adrenal (HPA) axis suppression and local adverse reactions. (2)
- Avoid use under occlusion or in the diaper area. (2)
- Locoid Lipocream is not for oral, ophthalmic, or intravaginal use. (2)

---------- DOSAGE FORMS AND STRENGTHS ----------
Cream, 0.1% (1 mg/g). (3)

---------- CONTRAINDICATIONS ----------
None. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Endocrine System Adverse Reactions:
  - Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur, with the potential for glucocorticosteroid insufficiency. Consider periodic evaluations for HPA-axis suppression if Locoid Lipocream is applied to large surface areas or used under occlusion. If HPA-axis suppression is noted, reduce the application frequency, discontinue use, or switch to a lower potency corticosteroid. (5.1, 8.4)
  - Systemic effects of topical corticosteroids may also include manifestations of Cushing's syndrome, hyperglycemia, and glucosuria. (5.1, 8.4)
  - Pediatric patients may be more susceptible to systemic toxicity due to their larger skin-surface-to-body-mass ratios. (5.1, 8.4)
- Ophthalmic Adverse Reactions: Topical corticosteroids, including Locoid Lipocream, may increase the risk of cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist. (5.2)
- Skin Infections: Initiate appropriate therapy if concomitant skin infections develop. (5.3)

---------- ADVERSE REACTIONS ----------
The most common adverse reactions (≥1%) are application site reactions. (6)

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.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Locoid Lipocream® (hydrocortisone butyrate) cream is indicated for:

- Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults.
- The topical treatment of mild to moderate atopic dermatitis in pediatric patients 3 months of age and older.

2 DOSAGE AND ADMINISTRATION

Recommended Dosage for Corticosteroid-Responsive Dermatoses

For corticosteroid-responsive dermatoses in adults, apply a thin layer to the affected skin areas 2 or 3 times daily, depending on the severity of the condition, and rub in gently.

Recommended Dosage for Atopic Dermatitis

For atopic dermatitis in patients 3 months of age and older, apply a thin layer to the affected skin areas 2 times daily and rub in gently.

Administration Instructions

- Discontinue therapy when control is achieved.
- If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Before prescribing for more than 2 weeks, weigh any additional benefits of extending treatment to 4 weeks against the risk of HPA-axis suppression and local adverse events *[see Warnings and Precautions (5.1)]*.
- Locoid Lipocream is not for oral, ophthalmic, or intravaginal use.
- Do not use Locoid Lipocream:
  - With occlusive dressings unless directed by a healthcare provider. Avoid use in the diaper area, as diapers or plastic pants may constitute occlusive dressings.
  - On the face, underarms, or groin areas unless directed by a healthcare provider.

3 DOSAGE FORMS AND STRENGTHS

Cream: Each gram contains 1 mg of hydrocortisone butyrate (0.1%) in a white to off-white hydrophilic cream base.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Endocrine System Adverse Reactions

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

Use of topical corticosteroids, including Locoid Lipocream, can cause systemic adverse reactions including HPA-axis suppression with the potential for clinical glucocorticosteroid insufficiency. Factors that predispose a patient to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Consider patients for periodic evaluation of the HPA axis. This may be done by using cosyntropin ($ACTH_{1-24}$) stimulation testing (CST). If HPA-axis suppression is noted, reduce the frequency of application or withdraw Locoid Lipocream, or substitute a less potent corticosteroid. Signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

Studies conducted in pediatric subjects demonstrated reversible HPA-axis suppression after use of Locoid Lipocream. Pediatric patients may be more susceptible than adults to systemic toxicity from equivalent doses of Locoid Lipocream due to their larger skin-surface-to-body-mass ratios *[see Use in Specific Populations (8.4), Clinical Pharmacology (12.2)]*.

Cushing's Syndrome, Hyperglycemia, and Glucosuria

Systemic adverse reactions of topical corticosteroids, including Locoid Lipocream, may also include manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.

Additional Considerations for Endocrine Adverse Reactions

Use of more than one corticosteroid-containing product at the same time may increase total systemic corticosteroid exposure.

Minimize systemic corticosteroid effects by mitigating the risk factors for increased systemic absorption and using Locoid Lipocream as recommended *[see Dosage and Administration (2)]*.

5.2 Ophthalmic Adverse Reactions

Use of topical corticosteroids, including Locoid Lipocream, may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported in postmarketing experience with the use of topical corticosteroid products *[see Adverse Reactions (6.2)]*.

Avoid contact of Locoid Lipocream with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.3 Skin Infections

Use of topical corticosteroids, including Locoid Lipocream, may delay healing or worsen concomitant skin infections. If skin infections are present or develop, use an appropriate antifungal, antibacterial or antiviral agent. If a favorable response does not occur promptly, discontinue use of Locoid Lipocream until the infection has been adequately controlled.

5.4 Allergic Contact Dermatitis

Use of topical corticosteroids, including Locoid Lipocream, can cause allergic contact dermatitis Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation. Such an observation should be corroborated with appropriate patch testing. Discontinue Locoid Lipocream if the diagnosis is established.

6 ADVERSE REACTIONS

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

- Endocrine system adverse reactions *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*
- Ophthalmic adverse reactions *[see Warnings and Precautions (5.2)]*
- Skin infections *[see Warnings and Precautions (5.3)]*
- Allergic contact dermatitis *[see Warnings and Precautions (5.4)]*

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 clinical practice.

The safety data derived from Locoid Lipocream clinical trials reflect exposure to Locoid Lipocream twice daily for up to 4 weeks in pediatric subjects 3 months of age and older with mild to moderate atopic dermatitis.

Table 1. Frequency of Adverse Reactions in Pediatric Subjects 3 Months of Age and Older with Mild to Moderate Atopic Dermatitis

	Locoid Lipocream (n=131)	**Vehicle (n=133)**
Application site folliculitis	1%	0.0%
Application site irritation	1%	0.0%
Acne	1	0.0%

6.2 Postmarketing Experience

The following adverse reactions have been reported during post approval use of topical corticosteroids, including Locoid Lipocream. 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.

Local Adverse Reactions: burning, itching, drying, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

Ophthalmic Adverse Reactions: blurred vision, cataracts, glaucoma, and increased intraocular pressure.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no controlled or large-scale epidemiologic studies with Locoid Lipocream use in pregnant women, and available data on hydrocortisone butyrate use in pregnant women have not identified a drug-associated risk for major birth defects, miscarriages or adverse maternal or fetal outcomes.

In animal reproduction studies, when administered subcutaneously or topically to pregnant rats, rabbits, and mice, hydrocortisone butyrate induced adverse reproductive and developmental outcomes, including abortion, fetal death, malformation, delayed ossification, decrease in fetal weight, and delay in sexual maturation *(see Data)*. The available data do not allow the calculation of relevant comparisons between the systemic exposure of hydrocortisone butyrate observed in animal studies and the systemic exposure that would be expected in humans after topical use of Locoid Lipocream.

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

Animal Data

Systemic embryofetal development studies were conducted in rats and rabbits. Subcutaneous doses of 0.6, 1.8, and 5.4 mg/kg/day hydrocortisone butyrate were administered to pregnant female rats during gestation days 6 – 17. In the presence of maternal toxicity, fetal effects noted at 5.4 mg/kg/day included increased ossification variations and unossified sternebra. No treatment-related embryofetal toxicity or malformation were noted at doses of 5.4 and 1.8 mg/kg/day, respectively.

Subcutaneous doses of 0.1, 0.2, and 0.3 mg/kg/day hydrocortisone butyrate were administered to pregnant female rabbits during gestation days 7 – 20. Increased abortion was noted at 0.3 mg/kg/day. In the absence of maternal toxicity, a dose-dependent decrease in fetal body weight was noted at doses ≥0.1 mg/kg/day. Embryofetal toxicities (reduction in litter size, decreased number of viable fetuses, and increased post-implantation loss) were noted at doses ≥0.2 mg/kg/day. Additional fetal effects included delayed ossification noted at doses ≥0.1 mg/kg/day and increased fetal malformations (primarily skeletal malformations) noted at doses ≥0.2 mg/kg/day. A dose at which no embryofetal toxicity or malformation was observed was not established in this study.

Additional systemic embryofetal development studies were conducted in rats and mice. Subcutaneous doses of 0.1 and 9 mg/kg/day hydrocortisone butyrate were administered to pregnant female rats during gestation days 9 – 15. In the presence of maternal toxicity, an increase in fetal death and fetal resorption and an increase in ossification of caudal vertebrae were noted at 9 mg/kg/day. No treatment-related embryofetal toxicity or malformation was noted at 0.1 mg/kg/day.

Subcutaneous doses of 0.2 and 1 mg/kg/day hydrocortisone butyrate were administered to pregnant female mice during gestation days 7 – 13. In the absence of maternal toxicity, an increased number of cervical ribs and one fetus with clubbed legs were noted at 1 mg/kg/day. No treatment-related embryofetal toxicity or malformation was noted at 1 and 0.2 mg/kg/day.

No topical embryofetal development studies were conducted with hydrocortisone butyrate cream. However, topical embryofetal development studies were conducted in rats and rabbits with a hydrocortisone butyrate ointment formulation. Topical doses of 1% and 10% hydrocortisone butyrate ointment were administered to pregnant female rats during gestation days 6 – 15 or pregnant female rabbits during gestation days 6 – 18. A dose-dependent increase in fetal resorption was noted in rabbits and fetal resorptions were noted in rats at the 10% hydrocortisone butyrate ointment dose. No treatment-related embryofetal toxicity was noted at the 1% hydrocortisone butyrate ointment dose in rats. A dose at which no embryofetal toxicity was observed in rabbits after topical administration of hydrocortisone butyrate ointment was not established. No treatment-related malformation was noted at a dose of 10% hydrocortisone butyrate ointment in rats or rabbits.

A peri- and postnatal development study was conducted in rats. Subcutaneous doses of 0.6, 1.8, and 5.4 mg/kg/day hydrocortisone butyrate were administered to pregnant female rats from gestation day 6 to lactation day 20. In the presence of maternal toxicity, a dose-dependent decrease in fetal weight was noted at doses ≥1.8 mg/kg/day). No treatment-related fetal toxicity was noted at 0.6 mg/kg/day. A delay in sexual maturation was noted at 5.4 mg/kg/day. No treatment-related effects on sexual maturation were noted at 1.8 mg/kg/day. No treatment-related effects on behavioral development or subsequent reproductive performance were noted at 5.4 mg/kg/day.

8.2 Lactation

Risk Summary

There are no data on the presence of hydrocortisone in human or animal milk, the effects on the breastfed infant, or the effects on milk production after treatment with Locoid Lipocream.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of Locoid Lipocream could result in sufficient systemic absorption to produce detectable quantities in human milk.

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

8.4 Pediatric Use

Corticosteroid-Responsive Dermatoses

The safety and efficacy of Locoid Lipocream for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses have not been established in pediatric patients.

Atopic Dermatitis

The safety and effectiveness of Locoid Lipocream for the topical treatment of mild to moderate atopic dermatitis have been established in pediatric patients 3 months of age and older. Use of Locoid Lipocream for this indication is supported by evidence from a multicenter, randomized, vehicle-controlled trial of 264 pediatric subjects 3 months of age and older *[see Clinical Studies (14)]*.

The safety and efficacy of Locoid Lipocream for the topical treatment of mild to moderate atopic dermatitis have not been established in pediatric patients younger than 3 months of age.

Endocrine Adverse Reactions

Eighty-six (86) subjects (between 5 months and 18 years of age) with moderate to severe atopic dermatitis affecting at least 25% of body surface area (BSA) treated with Locoid Lipocream 3 times daily for up to 4 weeks were assessed for HPA-axis suppression in two separate studies. . Five of the 82 evaluable subjects (6.1%) demonstrated evidence of suppression, where the criterion for defining HPA-axis suppression was a serum cortisol level of ≤18 mcg/dL after cosyntropin stimulation. At the first follow-up visit, approximately 1 month after the conclusion of treatment, cosyntropin stimulation results of all subjects had returned to normal, with the exception of one subject. This last subject recovered adrenal function by 65 days post-treatment *[see Clinical Pharmacology (12.2)]*.

Because of higher skin-surface-to-body-mass ratios, pediatric patients are at a greater risk than adults of HPA-axis suppression when they are treated with topical corticosteroids *[see Warnings and Precautions (5.1)]*. They are therefore also at a greater risk of glucocorticosteroid insufficiency after withdrawal of treatment and of Cushing's syndrome while on treatment. Manifestations of adrenal suppression in pediatric patients include low plasma cortisol levels in response to ACTH stimulation.

Linear growth retardation, delayed weight gain, and intracranial hypertension have also been reported in pediatric patients receiving topical corticosteroids. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

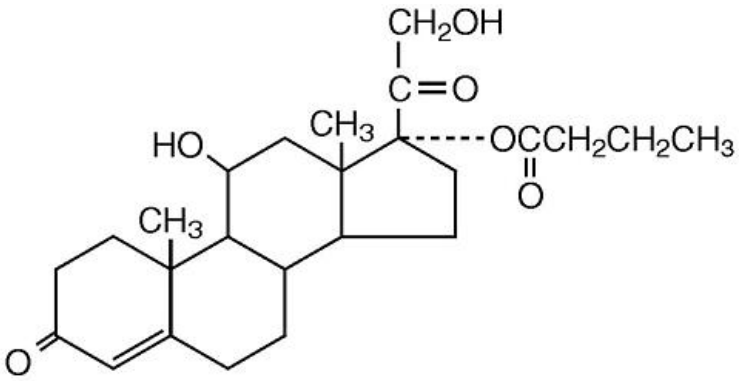
8.5 Geriatric Use

Clinical trials of Locoid Lipocream did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger adult subjects.

11 DESCRIPTION

Locoid Lipocream (hydrocortisone butyrate) cream, 0.1% contains hydrocortisone butyrate, a non-fluorinated hydrocortisone ester, for topical use. Hydrocortisone butyrate is a corticosteroid.

The chemical name of hydrocortisone butyrate is 11β,17,21-Trihydroxypregn-4-ene-3,20-dione 17-butyrate. It has the following structural formula:



Hydrocortisone butyrate is a white to off-white powder with a molecular weight of 432.56, and a molecular formula of $C_{25}H_{36}O_6$. It is practically insoluble in water, slightly soluble in ether, soluble in methanol, in alcohol, and in acetone, and freely soluble in chloroform.

Each gram of Locoid Lipocream contains 1 mg of hydrocortisone butyrate in a white to off-white hydrophilic cream base consisting of anhydrous citric acid, butylparaben, ceteth-20, cetostearyl alcohol, mineral oil, propylparaben, purified water, sodium citrate, and white petrolatum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action in atopic dermatitis is unknown.

12.2 Pharmacodynamics

Pharmacodynamics of Locoid Lipocream is unknown.

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

Eighty-six (86) subjects (between 5 months and 18 years of age) with moderate to severe atopic dermatitis affecting at least 25% of body surface area (BSA) treated with Locoid Lipocream 3 times daily for up to 4 weeks were assessed for HPA-axis suppression in two separate studies. The disease severity (moderate to severe atopic dermatitis) and the dosing regimen (3 times daily) in these HPA-axis trials were different from the subject population (mild to moderate atopic dermatitis) and the dosing regimen (2 times daily) for which Locoid Lipocream is indicated. Five of the 82 evaluable subjects (6.1%) demonstrated evidence of suppression, where the criterion for defining HPA-axis suppression was a serum cortisol level of ≤18 mcg/dL after cosyntropin stimulation. Suppressed subjects ranged in age from 5 months to 16 years and, at the time of enrollment, had 25% to 95% BSA involvement. These subjects did not demonstrate any clinical signs or symptoms despite evidence of HPA-axis suppression. At the first follow-up visit, approximately 1 month after the conclusion of treatment, cosyntropin stimulation results of all subjects had returned to normal, with the exception of one subject. This last subject recovered adrenal function by 65 days post-treatment *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*.

12.3 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed through normal intact skin. Inflammation and/or other disease processes in the skin, occlusive dressings, or widespread application may increase percutaneous absorption and increase the risk of HPA-axis suppression.

The vasoconstrictor assay showed that Locoid Lipocream had a more pronounced skin blanching effect than Locoid Cream, suggesting greater percutaneous absorption from the former.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year dermal rat carcinogenicity study with a hydrocortisone butyrate lotion formulation, hydrocortisone butyrate was administered to Sprague-Dawley rats at topical doses of 0.05, 0.15, and 0.3 mg/kg/day in males and 0.1, 0.25, and 0.5 mg/kg/day in females (0.1% lotion). No drug-related tumors were noted in this study up to the highest doses evaluated in this study of 0.3 mg/kg/day in males and 0.5 mg/kg/day in females.

Hydrocortisone butyrate revealed no evidence of mutagenic or clastogenic potential based on the results of two in vitro genotoxicity tests (Ames test and L5178Y/$TK^{+/-}$ mouse lymphoma assay) and one in vivo genotoxicity test (mouse micronucleus assay).

No evidence of impairment of fertility or effect on mating performance was observed in a fertility and general reproductive performance study conducted in male and female rats at subcutaneous doses up to 1.8 mg/kg/day. Mild effects on maternal animals, such as reduced food consumption and a subsequent reduction in body weight gain, were seen at doses ≥0.6 mg/kg/day.

14 CLINICAL STUDIES

In a multicenter, randomized, vehicle-controlled trial of 264 pediatric subjects 3 months age and older with mild to moderate atopic dermatitis, Locoid Lipocream or vehicle was applied twice daily for up to 4 weeks. Treatment success was assessed at Day 29 (after 28 days of treatment) and was defined as the proportion of subjects who achieved both “clear” or “almost clear” and at least a 2-grade improvement from baseline on a 5-point Physician’s Global Assessment (PGA) scale. The trial results are shown in Table 2.

Table 2. Efficacy Results at Day 29 in Pediatric Subjects 3 Months of Age and Older with Mild to Moderate Atopic Dermatitis

	Locoid Lipocream (n=131)	**Vehicle (n=133)**
Number (%) of successes	82 (63%)	37 (28%)

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Locoid Lipocream® (hydrocortisone butyrate) cream, 0.1% is white to off-white in color, and supplied in:

- tubes of 45 g: NDC 16781-384-45
- tubes of 60 g: NDC 16781-384-60

Storage and Handling

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from freezing.

17 PATIENT COUNSELING INFORMATION

Patients using Locoid Lipocream should receive the following information and instructions:

Administration Instructions *[see Dosage and Administration (2)]*

- *Corticosteroid-Responsive Dermatoses:*
  Instruct patients to apply a thin layer to the affected skin areas 2 or 3 times daily for corticosteroid-responsive dermatoses in adults and rub in gently.
- *Atopic Dermatitis:*
  Instruct patients to apply a thin layer to the affected skin areas 2 times daily for atopic dermatitis in patients 3 months of age or older and rub in gently.
- Advise patients to discontinue Locoid Lipocream when control is achieved.
- Instruct patients to contact their healthcare provider if no improvement is seen within 2 weeks.
- Advise patients to not *[see Warnings and Precautions (5.1)]:*
  - Bandage, otherwise cover, or wrap the affected skin area so as to be occlusive unless directed by their healthcare provider.
  - Use Locoid Lipocream in the diaper area, as diapers or plastic pants may constitute occlusive dressings.
  - Use Locoid Lipocream on the face, underarms, or groin areas unless directed by their healthcare provider.

Endocrine System Adverse Reactions

Advise patients to not use other corticosteroid-containing products while using Locoid Lipocream without first consulting their healthcare provider *[see Warnings and Precautions (5.1)]*.

Ophthalmic Adverse Reactions

Advise patients to avoid contact with the eyes. Instruct patients to report any visual symptoms to their healthcare providers *[see Warnings and Precautions (5.2)]*.

Lactation

Advise patients that are breastfeeding to use Locoid Lipocream on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise patients to wash off prior to breastfeeding any Locoid Lipocream that has been applied to the areas at risk for direct infant contact.*[see Use in Specific Populations (8.2)]*.

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Manufactured By:
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