



WILLIAM G. WILKOFF, M.D.

“Sarah, your son is doing very well. It looks like you are enjoying being a mother. Unless you are having trouble I won’t be seeing you until Clay’s 4-month visit. I know you said at the last visit that

you had your day care plans in order. Are they still solid?”

“Well . . . Dr. Wilkoff, being a mother has been much more fun than I expected. It is going to be very hard for me to go back to work and leave Clay with someone else. I’ve enjoyed nursing and although the schedule that my boss has agreed to should allow me to keep nursing, I just don’t want to look back a year

or 2 from now and regret having missed this special time.

“I never guessed that it would be like this. I enjoy my job. I never ever considered not going back to it. Jason and I have talked and looked at the numbers. He says he’s pretty sure we can make it on one income, and he thinks we should try it with me staying home. But I don’t know. I’m worried we won’t make it, and

I don’t want to have to ask our parents for help. What do you think, Dr. Wilkoff?”

I have stood at these crossroads that Sarah and Jason are facing dozens of times in my career. Usually, I am an interested, but mute bystander. But, every now and then I will be asked for my 2 cents.

Obviously, it’s difficult to give advice without knowing the details of a young family’s finances. Because in the end it is all about the money. Are they already living in a house with a mortgage that gobbles up too much of their incomes? Do they have other debt? Whose job is helping fund their health insurance?

But actually it isn’t all about the money. It’s about some important intangibles. How creative can this young couple be in cutting their expenses? Can they think far enough outside the box to get by with just one vehicle and no cable television? Will Jason have enough stamina to work more hours or find a part-time job? It sounds as though he is committed to the concept of Sarah’s staying home. His positive attitude alone suggests to me that this experiment is going to work.

Will Sarah have the stamina after a full day of mothering to work a few hours in the evening a couple of hours a week? Can she accept a part-time job that is well beneath her training and experience?

Even if they can make the new numbers work, will Sarah find a peer group that will support her decision to stay home? Thirty years ago I wouldn’t have thought to consider this question. But over the decades I have spoken to enough young mothers who have stayed home to hear that it can feel lonely at times without other women who share their perspective on the frustrations, fears, and successes of parenting.

If Sarah decides to quit her job and stay home, depending on her neighborhood, she will find herself in a small minority, maybe even alone. Will she find enough support to balance what she might perceive as a loss of status associated with stepping away from her career? I may be able to help by reminding her at each visit of the “firsts” she has witnessed by staying at home. And the control she has over things like Clay’s sleep schedule and TV exposure.

So what did I tell Sarah today? First, I reminded her that past performance is no guarantee of success, but that whenever family members have shared with me their concerns about this kind of decision it has always worked out. It’s not easy swimming against the societal norm, but I had a strong feeling that Sarah and Jason and Clay were going to make it work.

In the interest of gender equality, I must add that the arrangement can work well when the father is the parent who stays home. ■

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LETTERS FROM MAINE

A Surprise Decision

DESONATE® (desonide) Gel for topical use only
Initial U.S. Approval: 1972

BRIEF SUMMARY CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Desonate is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Patients should be instructed to use Desonate for the minimum amount of time as necessary to achieve the desired results because of the potential for Desonate to suppress the hypothalamic-pituitary-adrenal (HPA) axis [see Warnings and Precautions (5.1)]. Treatment should not exceed 4 consecutive weeks [see Dosage and Administration (2)].

4 CONTRAINDICATIONS

Desonate is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

5 WARNINGS AND PRECAUTIONS

5.1 Effects on Endocrine System

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

The effect of Desonate on HPA axis function was investigated in pediatric subjects, 6 months to 6 years old, with atopic dermatitis covering at least 35% of their body, who were treated with Desonate twice daily for 4 weeks. One of 37 subjects (3%) displayed adrenal suppression after 4 weeks of use, based on the cosyntropin stimulation test. As follow-up evaluation of the subject’s adrenal axis was not performed, it is unknown whether the suppression was reversible [see Use in Specific Populations (8.4) and Clinical Pharmacology (12.2)].

Pediatric patients may be more susceptible than adults to systemic toxicity from equivalent doses of Desonate due to their larger skin surface-to-body mass ratios [see Use in Specific Populations (8.4)].

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent steroids, use over large surface areas, use over prolonged periods, use under occlusion, use on an altered skin barrier, and use in patients with liver failure.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression. If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing’s syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.

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

5.2 Local Adverse Reactions with Topical Corticosteroids

Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include skin atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

5.3 Concomitant Skin Infections

If concomitant skin infections are present or develop during treatment, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of Desonate should be discontinued until the infection is adequately controlled.

5.4 Skin Irritation

If irritation develops, Desonate should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

6 ADVERSE REACTIONS

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

In controlled clinical studies of 425 Desonate-treated subjects and 157 Vehicle-treated subjects, adverse events occurred at the application site in 3% of subjects treated with Desonate and the incidence rate was not higher compared with vehicle-treated subjects. The most common local adverse events in Desonate treated subjects were application site burning in 1% (4/425) and rash in 1% (3/425) followed by application site pruritus in <1% (2/425).

Adverse events that resulted in premature discontinuation of study drug in Desonate treated subjects were telangiectasia and worsening of atopic dermatitis in one subject each. Additional adverse events observed during clinical trials for patients treated with Desonate included headache in 2% (8/425) compared with 1% (2/157) in those treated with vehicle.

The following additional local adverse reactions have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, secondary infection, skin atrophy, striae, and miliaria.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C:

There are no adequate and well-controlled studies in pregnant women. Therefore, Desonate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. No reproductive studies in animals have been performed with Desonate. Dermal embryofetal development studies were conducted in rats and rabbits with a desonide cream, 0.05% formulation. Topical doses of 0.2, 0.6, and 2.0 g cream/kg/day of a desonide cream, 0.05% formulation or 2.0 g/kg of the cream base were administered topically to pregnant rats (gestational days 6-15) and pregnant rabbits (gestational days 6-18). Maternal body weight loss was noted at all dose levels of the desonide cream, 0.05% formulation in rats and rabbits. Teratogenic effects characteristic of corticosteroids were noted in both species. The desonide cream, 0.05% formulation was teratogenic in rats at topical doses of 0.6 and 2.0 g cream/kg/day and in rabbits at a topical dose of 2.0 g cream/kg/day. No teratogenic effects were noted for the desonide cream, 0.05% formulation at a topical dose of 0.2 g cream/kg/day in rats and 0.6 g cream/kg/day in rabbits. These doses (0.2 g cream/kg/day and 0.6 g cream/kg/day) are similar to the maximum recommended human dose based on body surface area comparisons.

8.3 Nursing Mothers

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 corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Desonate is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of Desonate in pediatric patients less than 3 months of age have not been evaluated, and therefore its use in this age group is not recommended.

The effect of Desonate on HPA axis function was investigated in pediatric subjects, with atopic dermatitis covering at least 35% of their body, who were treated with Desonate twice daily for 4 weeks. One of 37 subjects (3%) displayed adrenal suppression after 4 weeks of use, based on the cosyntropin stimulation test [see Warnings and Precautions (5.1)].

In controlled clinical studies in subjects 3 months to 18 years of age, 425 subjects were treated with Desonate and 157 subjects were treated with vehicle [see Adverse Reactions (6) and Clinical Studies (14)].

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression when they are treated with topical corticosteroids. They are therefore also at greater risk of glucocorticosteroid insufficiency after withdrawal of treatment and of Cushing’s syndrome while on treatment.

Adverse effects, including striae, have been reported with inappropriate use of topical corticosteroids in infants and children. HPA axis suppression, Cushing’s syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

8.5 Geriatric Use

Clinical studies of Desonate did not include patients aged 65 and older to determine if they respond differently than younger patients. Treatment of this patient population should reflect the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic or photo-carcinogenic potential of Desonate or the effect of desonide on fertility. Desonide revealed no evidence of mutagenic potential based on the results of an *in vitro* genotoxicity test (Ames assay) and an *in vivo* genotoxicity test (mouse micronucleus assay). Desonide was positive without S9 activation and was equivocal with S9 activation in an *in vitro* mammalian cell mutagenesis assay (L5178Y/TK+ mouse lymphoma assay). A dose response trend was not noted in this assay.

17 PATIENT COUNSELING INFORMATION

Patients using topical corticosteroids should receive the following information and instructions:

- This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
- This medication should not be used for any disorder other than that for which it was prescribed.
- Unless directed by the physician, the treated skin area should not be bandaged or otherwise covered or wrapped so as to be occlusive.
- Unless directed by a physician, this medication should not be used on the underarm or groin areas of pediatric patients.
- Parents of pediatric patients should be advised not to use Desonate in the treatment of diaper dermatitis. Desonate should not be applied in the diaper area, as diapers or plastic pants may constitute occlusive dressing [see Dosage and Administration (2)].
- Patients should report to their physician any signs of local adverse reactions.
- Other corticosteroid-containing products should not be used with Desonate without first consulting with the physician.
- As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

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