

Topical Doxepin Prior Authorization with Quantity Limit Program Summary

FDA APPROVED INDICATIONS AND DOSAGE¹⁻³

Agent(s)	Indication(s)	Dosage & Administration
<p>Doxepin 5% cream</p>	<p>Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.*</p>	<p>A thin film of doxepin hydrochloride cream, 5% should be applied four times each day with at least a 3 to 4 hour interval between applications.</p> <p>There are no data to establish the safety and effectiveness of doxepin hydrochloride cream, 5% when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin hydrochloride cream, 5% for longer than 8 days may result in an increased likelihood of contact sensitization.</p> <p>Drowsiness is significantly more common in patients applying doxepin cream to over 10% of their body surface area.</p>
<p>Prudoxin™ (doxepin) cream 5%</p>	<p>Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.*</p>	<p>A thin film of doxepin hydrochloride cream, 5% should be applied four times each day with at least a 3 to 4 hour interval between applications.</p> <p>There are no data to establish the safety and effectiveness of doxepin hydrochloride cream, 5% when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin hydrochloride cream, 5% for longer than 8 days may result in an increased likelihood of contact sensitization.</p> <p>Drowsiness is significantly more common in patients applying doxepin cream to over 10% of their body surface area.</p>

Agent(s)	Indication(s)	Dosage & Administration
Zonalon® (doxepin) cream 5%	Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.*	<p>A thin film of doxepin hydrochloride cream, 5% should be applied four times each day with at least a 3 to 4 hour interval between applications.</p> <p>There are no data to establish the safety and effectiveness of doxepin hydrochloride cream, 5% when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin hydrochloride cream, 5% for longer than 8 days may result in an increased likelihood of contact sensitization.</p> <p>Drowsiness is significantly more common in patients applying doxepin cream to over 10% of their body surface area.</p>

*Pediatric use is not recommended. There was a case of a 2.5 year old who developed somnolence, grand mal seizure, respiratory depression, ECG abnormalities, and coma after treatment with doxepin cream.

CLINICAL RATIONALE

Atopic Dermatitis

Atopic dermatitis is a chronic, pruritic, inflammatory skin disease. Clinical features include skin dryness, erythema, oozing and crusting, and lichenification. Pruritus is responsible for much of the disease burden for patients. The goals of treatment are to reduce symptoms of pruritus and dermatitis, prevent exacerbations, and minimize therapeutic risks.⁵ Recommended topical therapy for atopic dermatitis includes topical corticosteroids, intralesional corticosteroids, as well as topical calcineurin inhibitors.^{4,6} While topical doxepin does provide short-term decrease in pruritus, it is not recommended for atopic dermatitis by the American Academy of Dermatology Association due to the risk of absorption and contact dermatitis.⁴ UptoDate lists topical doxepin as an option for treating atopic dermatitis pruritus after sedating and non-sedating antihistamines have failed.⁵

Lichen Simplex Chronicus

Lichen simplex chronicus is a secondary skin disorder that results from excessive scratching.⁶ Typically, lichenified plaques and excoriations are present.⁶ Patients typically complain of intense pruritus in the affected areas.⁶ The treatment of lichen simplex chronicus centers on the discontinuation of the itch/scratch cycle.^{6,7} Topical corticosteroids and intralesional corticosteroids are commonly used therapies.^{6,7} Oral antihistamines is a systemic option for less localized pruritus.^{6,7} Doxepin is an option for local treatment of pruritus.⁶

Safety

Doxepin cream is contraindicated in the following:¹

- Patients with untreated narrow angle glaucoma or a tendency to urinary retention.
- Individuals who have shown previous sensitivity to any of its components.

Prudoxin is contraindicated in the following:²

- Patients with untreated narrow angle glaucoma or a tendency to urinary retention.
- Individuals who have shown previous sensitivity to any of its components.

Zonalon is contraindicated in the following:³

- Patients with untreated narrow angle glaucoma or a tendency to urinary retention.
- Individuals who have shown previous sensitivity to any of its components.

REFERENCES

1. Doxepin prescribing information. Renaissance Pharma, Inc. February 2016.
2. Prudoxin prescribing information. Prestium Pharma, Inc. June 2015.
3. Zonalon prescribing information. PharmaDerm. March 2012.
4. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *Journal of the American Academy of Dermatology*. 2014 Feb;70(2):338-51.
5. Treatment of atopic dermatitis (eczema). UptoDate. Current through 6/2018. Last updated 5/22/2018. Accessed 7/23/2018.
6. Pruritus: overview of management. UptoDate. Current through 6/2018. Last updated 5/25/2018. Accessed 7/23/2018.
7. Lichen simplex (syn. circumscribed neurodermatitis). Primary Care Dermatology Society. Created 10/2013. Last updated 12/13/2016.

Topical Doxepin Prior Authorization with Quantity Limit

OBJECTIVE

The intent of the Topical Doxepin Prior Authorization (PA) and Quantity Limit (QL) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and according to dosing recommended in product labeling. For the diagnosis of moderate pruritus associated with atopic dermatitis, the program requires the patient to have tried a topical corticosteroid, topical calcineurin inhibitor, intralesional corticosteroid, or oral antihistamine; or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroids, topical calcineurin inhibitors, intralesional corticosteroids, and oral antihistamines. For the diagnosis of moderate pruritus associated with lichen simplex chronicus, the program requires the patient to have tried a topical corticosteroid, intralesional corticosteroid, or oral antihistamine; or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroids, intralesional corticosteroids, and oral antihistamines. The program will not allow approval for patients who have an FDA labeled contraindication to the requested agent, nor will it allow for the use of more than one targeted agent at a time, nor will it allow for durations longer than 8 days for a single course of therapy. The program will approve for doses within the set limit. Doses above the set limit will be approved if the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

TARGET AGENTS

Doxepin 5% cream

Prudoxin (doxepin 5% cream)

Zonalon (doxepin 5% cream)

PRIOR AUTHORIZATION TARGET AND QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity Limit
Doxepin 5% cream	90220015103710	M, N, O, Y	45 g every 30 days ^a
Prudoxin 5% cream	90220015103710	M, N, O, Y	45 g every 30 days ^a
Zonalon 5% cream	90220015103710	M, N, O, Y	45 g every 30 days ^a

a – quantity limit is cumulative across agents

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Target Agents will be approved when ALL of the following are met:

1. The patient is an adult

AND

2. ONE of the following:

- a. The patient has a diagnosis of moderate pruritus associated with atopic dermatitis **AND** ONE of the following:

- i. The patient's medication history includes the use of a topical corticosteroid, intralesional corticosteroid, topical calcineurin inhibitor, or oral antihistamine in the past 90 days

OR

- ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroids, intralesional corticosteroids, topical calcineurin inhibitors, **AND** oral antihistamines

OR

- b. The patient has a diagnosis of moderate pruritus associated with lichen

simplex chronicus **AND** ONE of the following:

i. The patient's medication history includes the use of a topical corticosteroid, intralesional corticosteroid, or oral antihistamine in the past 90 days

OR

ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroids, intralesional corticosteroids, AND oral antihistamines

OR

c. The patient has another FDA approved indication for the requested agent

AND

3. ONE of the following:

a. The patient is not concurrently using another topical doxepin agent

OR

b. The patient will discontinue the other topical doxepin agent prior to starting therapy with the requested agent

AND

4. The patient has not already received 8 days of therapy with a topical doxepin agent for the current course of therapy

AND

5. The patient does NOT have any FDA labeled contraindication(s) to the requested agent

AND

6. ONE of the following:

a. The requested quantity (dose) is NOT greater than the program quantity limit

OR

b. BOTH of the following:

i. The requested quantity (dose) is greater than the program quantity limit

AND

ii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months