



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Doxepin cream is a topical medication used for the short-term treatment of pruritus (itching of the skin) due to atopic dermatitis (eczema) or lichen simplex chronicus (thickening of skin due to prolonged itching and scratching). Although doxepin does have H1 and H2 histamine receptor blocking actions, the exact mechanism by which doxepin exerts its antipruritic effect is unknown. Possible adverse reactions include, but are not limited to: drowsiness, urinary retention, increased pruritus, and contact sensitization (1-2).

Regulatory Status

FDA-approved indications: Doxepin cream 5% is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus (1-2).

Doxepin has an anticholinergic effect and significant plasma levels of doxepin are detectable after topical doxepin cream application, the use of doxepin cream is contraindicated in patients with untreated narrow angle glaucoma or a tendency to urinary retention (1-2).

A thin film of doxepin cream should be applied four times each day with at least a 3 to 4 hour interval between applications. There are no data to establish the safety and effectiveness of doxepin cream when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided (1-2).

Doxepin cream 5% criteria was created with dosing above FDA recommended limits in order to help existing patients that have been taking doses above the FDA recommended limits to safely taper down their doses to the appropriate levels. This will allow physicians to time to work with their patients in creating a custom taper that is safe and provides adequate relief from pruritus.

The safety and effectiveness of doxepin cream 5% in pediatric patients under 18 years of age has not been established (1).

Summary

Doxepin cream is a topical medication used for the short-term treatment of pruritus (itching of the



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DOXEPIN CREAM 5% (Prudoxin, Zonalon)

skin) due to atopic dermatitis (eczema) or lichen simplex chronicus (thickening of skin due to prolonged itching and scratching). Although doxepin does have H1 and H2 histamine receptor blocking actions, the exact mechanism by which doxepin exerts its antipruritic effect is unknown. There are no data to establish the safety and effectiveness of doxepin cream when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of doxepin cream 5% while maintaining optimal therapeutic outcomes.

References

1. Zonalon Cream [package insert]. San Antonio, TX: DPT Laboratories Ltd.; June 2017.
2. Prudoxin Cream [package insert]. San Antonio, TX: DPT Laboratories Ltd. June 2017.