



Prescribers are recommended to consult the summary of product characteristics before prescribing.

Abridged Prescribing Information - Xepin 5% w/w Cream:

Presentation: White emollient cream containing 5% w/w doxepin hydrochloride.

Uses: For the relief of pruritus associated with eczema.

Dosage and Administration: Adults, Elderly and children over 12 years: A thin film of Xepin should be applied three to four times daily, to the affected area only. Clinical experience has shown that drowsiness is significantly more common in patients applying cream to more than 10% of the body surface area, therefore, the maximum coverage should be less than 10% of body surface area. For an average sized patient, this would equate to 3g of Xepin per application and not more than 12g of Xepin per day. If excessive drowsiness does occur, it may be necessary to reduce the number of applications, the amount of cream applied and/or the percentage of body surface area treated. Children under 12 years: Not recommended.

Contra-indications: Known hypersensitivity to any of its components.

Special Warnings and Precautions for Use: Drowsiness may occur with the use of Xepin. Clinical trial data demonstrate that drowsiness is observed principally in patients receiving treatment to greater than 10% of body surface area and that drowsiness is transient, usually remitting after the first few days of treatment. Patients should be warned of this possibility and cautioned against driving or operating machinery if they become drowsy. Patients should also be warned that the effects of alcohol could be potentiated. In view of the known adverse effects of orally administered doxepin hydrochloride, Xepin should be used with caution in patients with the following conditions: glaucoma, a tendency to urinary retention, severe liver disease, mania, or severe heart disease including those prone to cardiac arrhythmias. Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis). **Interactions with other medicinal products:** Alcohol ingestion may exacerbate the potential sedative effects of Xepin particularly in those individuals who use alcohol excessively. MAO inhibitors should be discontinued at least two weeks prior to the initiation of treatment with Xepin since serious interactions have been reported between orally administered doxepin hydrochloride and MAO inhibitors. As doxepin is metabolised via hepatic microsomal enzymes, care should be taken when co-prescribing any other medicines which are also metabolised by this route. Caution should also be exercised in patients being treated with cimetidine since it has been found to affect serum concentrations of orally administered tricyclic antidepressants, such as doxepin hydrochloride. Oral doxepin hydrochloride is known to interact with sympathomimetic agents and may increase the risk of arrhythmias and hypotension or hypertension with general and local anaesthetics. In view of the small but noteworthy amount of systemic absorption following topical administration of Xepin caution should be exercised with these agents. **Pregnancy and breast-feeding:** Xepin should only be used in pregnancy and lactation if, in the clinician's judgement, the benefits outweigh the risks.

Side Effects: Drowsiness has been reported in clinical trials, with an incidence of 12-19%. It is generally of mild to moderate severity and of short duration. Limiting treated body surface to less than 10% minimises the risk of drowsiness. Local adverse reactions have been reported and may occur more frequently with the use of occlusive dressings. Local reactions, in decreasing order of frequency, include burning, stinging, irritation, tingling and local rash. Systemic effects, observed with orally administered doxepin hydrochloride are rarely observed with topical Xepin. These may include anticholinergic effects (dry mouth, changes in taste, dry eyes, blurred vision, urinary retention); central nervous system effects other than drowsiness (headaches, fever, dizziness); and gastrointestinal effects (nausea, indigestion, vomiting and diarrhoea or constipation). Cases of suicidal ideation and suicidal behaviours have been reported during oral doxepin hydrochloride therapy or early after treatment discontinuation.

Legal Category: POM **NHS Price:** £13.66 (30g) **MA Number:** PL 16794/0008

Marketing Authorisation Holder: Cambridge Healthcare Supplies Ltd., Unit 1 Chestnut Drive, Wymondham, Norfolk, NR18 9SB.

Tel: 01953 607856 **Fax:** 01953 713649 **E-mail:** marketing@chsl.co.uk

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Cambridge Healthcare Supplies Limited.

1XEP12/1909

¹ Breneman DL, Dunlap FE, Monroe EW et al. Doxepin cream relieves eczema-associated pruritus within 15 minutes and is not accompanied by a risk of rebound upon discontinuation. *J Dermatol Treat.* 1997;8:161-168

² Cocks-Eschler D & Klein P J. *Drugs in Dermatology.* (Aug 2010). Vol 9 (8)

³ Millington GWM et al British Association of Dermatologists' guidelines for the investigation and management of generalized pruritus in adults without an underlying dermatosis, 2018. *British Journal of Dermatology* (2018) 178, pp34-60

Xepin

5% w/w Cream

(doxepin hydrochloride)

**The only clinically proven
topical Antihistaminic Agent²**



Stop the itch-scratch cycle
at the first sign of a flare up

A GUIDE FOR HEALTHCARE PROFESSIONALS

Xepin
5% w/w Cream
(doxepin hydrochloride)



Stop the itch-scratch cycle
at the first sign of a flare up



The only clinically proven topical Antihistaminic Agent²

Specifically formulated to reduce adult itch

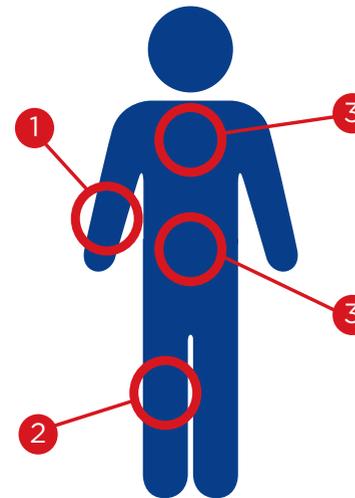
- Onset of itch reduction within 15 minutes¹
- Alternative to oral anti-histamine tablets
- Targeted, not central antipruritic effect¹
- No rebound on discontinuation¹ - suitable for intermittent use, prior to and during flares
- Potent H1 & H2 receptor antagonist¹

EFFECTIVE¹

75% of patients have a significant reduction in itch after 15 minutes

TOLERABLE

Does not contain steroids, parabens or perfume



10% of the body surface area is roughly equal to

1) one whole arm,

2) the front or back of a leg

3) half of the torso

This 10% can be made up by several smaller hot spots (e.g. your knees, face or hands)

Lifestyle

Controlling flare-ups.
Start with identifying and avoiding eczema triggers and irritants to the skin

Emollients

These help to rehydrate the skin and should be used regularly



Xepin 5% w/w cream

Apply specially formulated topical anti-histamines to stop the itch/scratch cycle



Steroid Creams

Different strengths available to tackle the inflammation



Additional information leaflets to give your patient with their prescription can be requested via: marketing@chsl.co.uk