

Combined photocontact dermatitis to benzydamine hydrochloride and the emulsifiers, Span 60 and Tween 60 contained in Tantum[®] cream

Contact Dermatitis 2007; 57: 61–62

Ana Giménez-Arnau¹, Montserrat Gilaberte¹,
David Conde², Mercè Espona² and
Ramon M. Pujol¹

¹Department of Dermatology and

²Department of Pharmacy, Hospital del Mar,
IMAS, Universitat Autònoma de Barcelona,
Barcelona, Spain

Key words: benzydamine hydrochloride; emulsifiers; photocontact dermatitis; Span₆₀; Tween₆₀.

Benzydamine is an indazol compound with analgesic, anti-inflammatory and anaesthetic properties. Topical application includes cream or gel preparations as well as mouth-washes and vaginal irrigations. Either allergic contact dermatitis or photoallergic reactions to benzydamine have occasionally been described (1, 2). Exceptionally, the vehicle of a benzydamine cream has been shown to be responsible for contact eczema (3).

A 73-year-old woman presented an acute-onset photodistributed eczematous eruption beginning 5 days before consultation. Her past medical history included type II diabetes mellitus and hypothyroidism. For 3 days before the onset of the rash, she had applied, twice a day, Tantum[®] cream containing benzydamine hydrochloride at 3% for treating a non-specific

mechanical neck pain. Physical examination disclosed an eczematous eruption involving both cheeks, the anterior and lateral aspects of the neck, upper chest, and back. Open wet dressing and topical corticosteroids were prescribed and a progressive improvement of the eruption was noted.

She was initially studied with the Spanish GEIDAC standard series. Patch and photopatch tests with non-steroidal anti-inflammatory drug series (including benzydamine chloride 1% pet.) provided by Marti-Tor[®] and Tantum cream[®] were also performed. A positive nickel sulfate reaction was

observed. Tantum cream[®] (Barcelona, Spain) patch test showed a doubtful positivity, while the photopatch turned out to be clearly positive (Table 1).

Tantum cream[®] components [benzydamine hydrochloride 10%, 1%, 0.1%, cetyl alcohol 30% in pet., white FU petroleum jelly, Span 60 (Sorbitom TE) 1%, 10% and 50% pet., Tween 60 (Sorbitom SE) 20% pet., and propylene glycol (FU propylene glycol) 5% aq.] kindly provided by Farma Lepori S.A. were also patch and photopatch tested. Trolab cetyl alcohol (20% pet.) and propylene glycol (5% pet.) were also tested. Just positive photopatch tests reactions to benzydamine hydrochloride (10% pet.), Span 60 (10–50% pet.) and Tween 60 (20% pet.) were noted (Fig. 1 and Table 1). 20 controls were submitted to the same protocol and no positive reactions were observed.

Comment

Fatty acid esters of sorbitan (Span₆₀) and their ethoxylated derivatives (Tween₆₀) are commonly used as non-ionic surfactants. They are widely employed in cosmetics and some pharmaceutical products. Span 60 and Tween 60 are approved for use in foodstuffs. Emulsifiers are uncommon causes of allergic contact dermatitis. When present, contact



Fig. 1. Photopatch test performed with Tantum[®] cream constituents. Benzydamine hydrochloride at 10%, Span 60 (Sorbitom TE) at 50% and 10% and Tween 60 (Sorbitom SE) turned out positive.

Table 1. Patch and photopatch results to Tantum cream[®] and its components. Summary of the most relevant readings

Tested substance	Patch test ^a	Photopatch test ^b
Tantum cream [®]	Doubtful ^c	++
Benzydamine chloride, 1% pet. ^c	Negative	Negative
Benzydamine hydrochloride, 10% pet. ^d	Negative	++
Benzydamine hydrochloride, 1% pet. ^d	Negative	Negative
Benzydamine hydrochloride, 0.1% pet. ^d	Negative	Negative
Tween 60 (Sorbitom SE) 20% pet. ^d	Negative	++
Span 60 (Sorbitom SE), 50% pet. ^d	Negative	++
Span 60 (Sorbitom SE), 10% pet. ^d	Negative	++
Span 60 (Sorbitom SE), 1% pet. ^d	Negative	Negative

^aFive-day reading.

^bUVA 5 J/cm² delivered 15 min. Waldmann 800 (Waldmann Lighting, USA).

^cSupplied by Marti-Tor S.L (Barcelona, Spain).

^dSupplied by Farma Lepori S.A.

^eErythematous positive patch- test.

dermatitis occurs along with sensitization to the active ingredient contained in the formulation that they are a part of. Conversely, they are well-known skin irritants.

Sensitization to Span 80 and Tween 80 has been described in the context of polysensitization but for Span 60 only a few cases of allergic contact dermatitis have been reported (4, 5). Reviewing the literature, there is only one report of contact urticaria from Tween 60 contained in a 1% hydrocortisone cream (6). Neither Span 60 nor Tween 60 have been described previously as photosensitizers. Nevertheless benzidamine is a well-known photosensitizing drug (5% pet.).

As far as we are concerned, the observation of associated positive photopatch tests reactions to benzydamide, Span 60 and Tween 60, along with to Tantum cream[®] has not been previously reported.

Our observation supports the interest in performing a systematic evaluation of possible photoallergic reactions to all the constituents (vehicles, surfactants) of a well-known potential photosensitive formulation, even in cases either showing negative or positive photopatch test results to the active drug.

Tel: 34932099936
Fax: 34934144909
e-mail: 22505aga@comb.es

References

1. Ikemura I. Contact and photocontact dermatitis due to benzydamine hydrochloride. *Jpn J Clin Dermatol* 1971; 25: 129.
2. Fernandez de Corres L. Photodermatitis from benzydamine. *Contact Dermatitis* 1980; 6: 285.
3. Goday Buján J J, Ilardia Lorentzen R, Soloeta Arechavala R. Allergic contact dermatitis from benzydamine with probable cross-reaction to indomethacin. *Contact Dermatitis* 1993; 28: 111–112.
4. Pasche-Koo F, Piletta P A, Hunziker N, Hauser C. High sensitization rate to emulsifiers in patients with chronic leg ulcers. *Contact Dermatitis* 1994; 31: 226–228.
5. Hannukela M, Kousa M, Pirila V. Contact sensitivity to emulsifiers. *Contact Dermatitis* 1976; 2: 201–204.
6. Maibach H, Conant M. Contact urticaria to a corticosteroid cream: polysorbate 60. *Contact Dermatitis* 1977; 3: 350–351.

Address:
Ana Giménez-Arnau
Department of Dermatology
Hospital del Mar
Passeig Marítim 25-29
08003 Barcelona
Spain