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Omeprazole is a drug introduced in the market since 1979. It belongs to the benzimidazole group and acts as an inhibitor of the proton pump. It is administered orally and has a wide use in the treatment of the peptic acid disease and Zollinger Ellison syndrome and as a protector of the gastric mucosae in patients with surgical stress and with background of taking multiple medications. Allergic contact dermatitis due to omeprazole has not been frequently reported.

Meding (1) in 1986 reported for the first time 2 occupational cases in pharmaceutical workers. Lesions were localized to the eyelids, and patch testing showed positive reactions to omeprazole.

The concentrations of omeprazole used in 1 patient were 0.25%, 0.5%, and 1% in pet. Control test with omeprazole 0.5% in pet. in 10 persons were negative.

The second patient was tested with omeprazole 0.1%, 0.5%, and 1% in alcohol. Control test with omeprazole 0.5% in alcohol in 12 individuals were negative.

After this report, we have no knowledge of any other cases of occupational dermatitis from omeprazole.

Case Report

Case 1

A 25-year-old man with personal and family history of atopy, who worked in a pharmaceutical company for 5 years, was exposed to substances used in the manufacture omeprazole capsule.

In the first step, omeprazole is added as a powder into a hopper of a mixer, after which the substances in column A of Table 1 are added and mixed. In the second step, ingredients mentioned in column B of Table 1 are also added.

The patient used only latex gloves as protective equipment (not mask, overalls, or glasses). Even though there is no

Occupational airborne contact dermatitis from omeprazole

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Table 1. Excipients in omeprazole manufacture

A	B
Avicel	Glycine
Mannitol	Arginine
Croscarmellose	Texapone Z
LH21 (hydroxypropylcellulose)	Magnesium carbonate
	Polyvinylpyrrolidone K30
	Polysorbate 80

In omeprazole capsule manufacturing, the substances in column A are first mixed. Then, substances in column B are added.

Table 2. Patch testing results

	Case 1		Case 2	
	Day 2	Day 4	Day 2	Day 4
Standard series				
Potassium dichromate	—	—	++	++
Omeprazole 0.1% in alcohol	++	++	—	—
Omeprazole 0.5% in alcohol	++	++	++	++
Avicel 1% in aq	—	—	—	—
Avicel 5% in aq	—	—	—	—
Mannitol 1% in aq	—	—	—	—
Mannitol 5% in aq	—	—	—	—
Croscarmellose 1% in aq	—	—	—	—
Croscarmellose 5% in aq	—	—	—	—
Hydroxypropylcellulose 1% in aq	—	—	—	—
Hydroxypropylcellulose 5% in aq	—	—	—	—
Glycine 1% in aq	—	—	—	—
Glycine 5% in aq	—	—	—	—
Arginine base 1% in aq	—	—	—	—
Arginine base 5% in aq	—	—	—	—
Texapone 1% in aq	IR	IR	IR	IR
Texapone 5% in aq	IR	IR	IR	IR
Magnesium carbonate 1% in aq	—	—	—	—
Magnesium carbonate 5% in aq	—	—	—	—
Polyvinylpyrrolidone 1% in aq	—	—	—	—
Polyvinylpyrrolidone 5% in aq	—	—	—	—
Polysorbate 80 1% in aq	—	—	—	—
Polysorbate 80 5% in aq	—	—	—	—

aq = water, IR = irritant reaction.

direct contact with any of these substances, most of the powdered raw materials dust the working environment producing an airborne exposure.

The patient was referred to our department because of skin lesions that lasted for 6 weeks and manifested as 2 episodes of pruritic skin lesions. At first, only the eyelids were affected; later, besides the face, neck and hands were also involved and were characterized by eczematous plaques (erythema and oedema), suggesting an airborne contact mechanism. The patient was treated with topical corticosteroids and was on sick leave while patch testing was done, presenting healing of the dermatoses.

Patch testing was done with Grupo Español de Investigación Dermatitis de Contacto (GEIDC) standard series, omeprazole 0.1%, 0.5% in alcohol as well as with various exci-

pients (Table 2). Reading of test reactions was done at days 2 and 4. The sites showed positive reactions to omeprazole.

Case 2

The patient was a 35-year-old man with diabetes treated with insulin. He works as supervisor at the same pharmaceutical company. His activities consisted visiting different areas of medicament production, without using protective measures (glasses, mask). Earlier, he worked in the building industry.

He developed itchy dermatitis that lasted for 6 months, affecting the eyelids, nose, and perioral area, characterized by eczematous plaques (Fig. 1).

Dermatitis cleared during holidays and worsened when he resumed his work, particularly during supervision of the area of omeprazole production.

Patch testing was done with GEIDC standard series, with omeprazole 0.1%, 0.5% in alcohol, and with 10 excipients at 2 different concentrations (Table 2). Reading of the patch test reactions was done at days 2 and 4.

He developed positive reactions to omeprazole and potassium dichromate, the latter interpreted as past relevance because of the previous exposure to cement.

Both patients had become free from skin lesions since they changed the job posts.

Patch tests with omeprazole at 0.1% and 0.5% concentrations in alcohol were negative in 10 controls.

Discussion

Meding (1) suggests that the sensitizing potential of the medicament should be investigated, in order to avoid future skin problems especially in individuals occupationally exposed as well as in patients treated with this drug.

Experimental animal studies were done and published later by

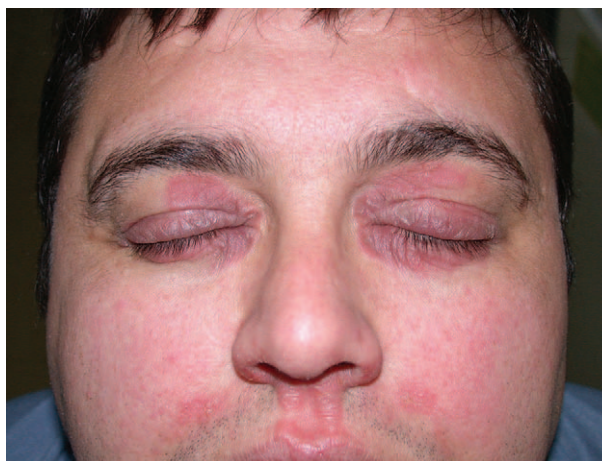


Fig. 1. Airborne contact dermatitis due to omeprazole. Clinical aspect of the lesions.

Hausen et al. (2) who concluded that omeprazole and other proton pump inhibitors such as pantoprazole and rabeprazole constitute a high-sensitizing-potential group of chemicals.

Furthermore, they concluded that the usual route of administration of the medicament, orally or parenterally, explains the low frequency of contact sensitization.

From the occupational point of view, we can draw the following conclusions:

- (1) The number of laboratories engaged in the processing of this medicament is scarce, and maybe the production is limited just to a few pharmaceutical companies.
- (2) There are few cases of contact allergy to omeprazole because some of them may be labelled as other kinds of eczema.

Individuals occupationally exposed to omeprazole, as in the present cases and those reported by Meding, may represent optimal environmental conditions for sensitization to omeprazole. In spite that direct contact with the skin is not always present, distribution of dust through the air and deposition on exposed areas and natural skin folds may result in an airborne pattern of contact dermatitis.

It should be compulsory to use protective equipment, including overalls, mask, and gloves, in order to avoid new cases of this kind of dermatitis such as the one described in this study.

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