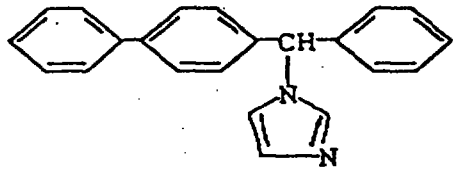
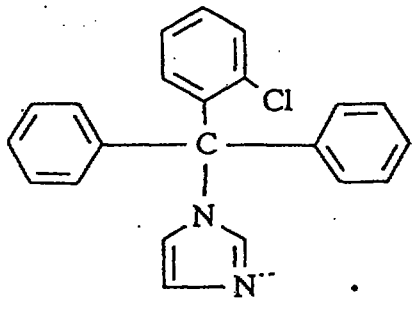
Formulations containing azole derivatives and their use for atraumatic nail removal

The invention relates to formulations containing azole derivatives and to their use for atraumatic nail removal and to a process for the preparation of these formulations.

Azole derivatives which may be mentioned are bifonazole of the formula



and clotrimazole of the formula



Formulation bases or formulations containing azole derivatives have been disclosed in US-A-4,070,451, EP-A-0,106,173, Dermatologica 1984, 169, Suppl. 1, 117 - 120, ibid. 1982, 165, C1, 54 - 61 and Cutis, 4, 1983, 31, 38 - 40. However, these are either not suitable for atraumatic nail removal or the formulations are not sufficiently stable.

It has been found that formulations which contain these azole derivatives in amounts of 0.05 - 1.5, preferably of 0.1 - 1, in particular of one part by weight and furthermore consist of

a) 40 parts by weight of urea
b) 20 parts by weight of anhydrous wool fat,
c) 5 parts by weight of bleached wax and
d) 34 parts by weight of white petroleum jelly,

have an excellent storage stability and are very highly suitable for atraumatic nail removal.

The formulations according to the invention can be prepared by mixing the anhydrous wool fat, the bleached wax and the white petroleum jelly at elevated temperature, for example at 50 - 80°C, and then adding the azole derivative and the urea. Preferably, the urea is added last.

The formulation according to the invention can be employed for atraumatic nail removal in the case of onychomycoses in humans and animals.

The azole derivatives display their antimycotic action in the formulation according to the invention by improved penetration into the nail infected by mycoses for the period up to nail removal. On account of its hydrating and keratolytic properties, urea causes a loosening and subsequent atraumatic detachment of the infected nail plate. The following experiment illustrates this.

The composition according to the example is applied every 24 hours to the fungus-infested nail and left for 24 hours under an occlusive dressing. By this process, the fungus-infected nail can as a rule be atraumatically detached in a period of between 6 to 10 days.

Example

Bifonazole	1 %
Urea	40 %
Wool fat, anhydrous	20 %
Bleached wax	5 %
Petroleum jelly, white	34 %
	100 %

Patent Claims

1. Formulations, characterised in that they consist of 0.05 - 1.5 parts by weight of bifonazole and/or clotrimazole, 40 parts by weight of urea, 20 parts by weight of anhydrous wool fat, 5 parts by weight of bleached wax and 34 parts by weight of white petroleum jelly.

2. Formulations according to Claim 1 for atraumatic nail removal.

3. Process for the preparation of formulations according to Claim 1, characterised in that the anhydrous wool fat, the bleached wax and the white petroleum jelly are mixed at elevated temperature and the bifonazole and/or clotrimazole and the urea are then added.