

DO. TOBELL S.r.l.

36030 Sarcedo (VI) - Italy

Technical sheet: Antifungal plasters

DOCUMENT No.: M4.9-1

edition no. 02 of 12.11.2020

Customer: BNB Facilities Inc

Date: 6 Juli 2021

Our Ref.: 224V24DA

Yr. Ref.: Fungus Plaster

Intended use: for the topical treatment of mycosis on toenails and fingernails. Onychomycosis (or nail mycosis) is an infection affecting one or more nails and is caused by a fungus: it is generally not a dangerous disorder, yet it is an unesthetic problem that can become difficult to treat, especially when neglected.

Classification: Non-invasive devices, class I, Rule I of the European Directive 93/42/EEC: "All non-invasive devices are in class I unless one of the rules set out hereinafter applies".

General information: The medical device is in conformity to Annex I (RES) of the European Directive 93/42/EEC. The Risk Management is developed in conformity to UNI EN ISO 14971:2012. The Medical Device is manufactured in Do. Tobell, that has developed and maintains a Quality Management System following UNI EN ISO 13485:2016.

Technical Information

Rose Felt:

composition	100% cotton
weight	186 gr./m ² (± 10%)
colour	rose

Adhesive support:

composition	100% Rubber
Loop tack test	5 N/25 mm. (± 2)
Peel adhesion test	10 N/25 mm. (± 2)
adhesive viscosity	150000 CPs (± 30000)
adhesive coat weight	270 gr./m ² (± 10)

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Composition adhesive mass: Excipients Natural gum
Natural e synthetic resins
Antioxidant - (iso-hexane)
Active ingredient Urea 37- 40%
on the solid part

Skin tolerability : hypo allergenic

Fixing: TNT No-woven fabric
polypropylene
Skin colour; beige

Thickness 0,22 mm (±15%)

Adhesive Acrylic Hypoallergenic adhesive
Solvent based hydrogenated resins
Natural rubber

Skin tolerability : hypo allergenic

Transparent film: Polyester PET
weight 135 gr./m² (+/-6%)
thickness 0,1 mm (+/-5%)

It does neither contain PCP nor nitrogenous colorants forbidden in Europe.

Written and checked by: QA A. Vecchiato

Signature: 