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Candida Albicans (Candin)

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Local reactions to CANDIN® (candida albicans) have included swelling, pruritus and vesiculation. Reactions involving necrosis and ulceration have not been observed, but such reactions are theoretically possible and might occur in persons with exquisite cellular hypersensitivity to the antigen. Local reactions may be treated with a cold compress and topical steroids. Severe local reactions may require additional measures as appropriate.

In a published study (13) of 479 HIV positive adults tested with CANDIN® (candida albicans) , adverse local reactions were observed in six subjects as follows: pruritus (three), swelling at the test site (one), vesiculation (one) and vesiculation with weeping edema (one). Pruritus and swelling cleared within 48 hours; vesiculation with edema required approximately 1 week to resolve (15).

in Tables 1, 2, 3, and text, one adverse reaction was observed. This reaction **CLINICAL PHARMACOLOGY** In two studies involving 171 persons discussed under consisted of induration 22 x 55 mm at 48 hours which resolved within 1 week (15).

Testing of CANDIN® (candida albicans) for consistency of potency is performed in healthy human subjects who are known to be skin-test positive to the antigen. In 58 subjects tested to-date, there have been no cases of Type 1 allergy manifested as either generalized or adverse local reactions. One subject had induration with a central vesicle which subsided within a few days (15).

Severe local reactions, including rash, vesiculation, bullae, dermal exfoliation and cellulitis, have been reported to MedWatch for unstandardized allergenic extracts used for anergy testing (17). *Candida albicans*of

Systemic reactions to CANDIN® (candida albicans) have not been observed. However, all foreign antigens have the remote possibility of causing Type 1 anaphylaxis (14) and even death when injected intradermally. Systemic reactions usually occur within 30 minutes after the injection of antigen and may include the following symptoms: sneezing, coughing, itching, shortness of breath, abdominal cramps , vomiting, diarrhea, tachycardia, hypotension and respiratory failure in severe cases. Systemic allergic reactions including anaphylaxis must be immediately treated with Epinephrine HCL 1:1,000. Additional measures may be required, depending upon the severity of the reaction.

reactions to CANDIN® (candida albicans) occur in some individuals. These reactions are characterized by the presence of an **Immediate Hypersensitivity** edematous hive surrounded by a zone of erythema. They occur approximately 15 - 20 minutes after the intradermal injection of the antigen. The size of the immediate reaction varies depending upon the sensitivity of the individual. Immediate hypersensitivity reactions were observed in the control and HIV-infected (AIDS (20% with erythema of 10 - 21 mm in diameter; 13% with erythema of 5 - 9 mm). **HIV-infected subjects**and HIV positive) subjects reported in Table 2 as follows: (Group 1, Table 3), 17% with erythema of 10 - 24 mm and **Cancer subjects** (22% with erythema of 10 - 15 mm; 5% with erythema of 8.5 mm). **Control subjects** 11% with erythema of 6 - 9 mm.