Spher·u·sol®
(Coccidioides immitis)
Spherule-Derived Skin Test Antigen

SPHERUSOL® (*Coccidioides immitis*) Spherule-Derived Skin Test Antigen

A highly sensitive and specific skin test antigen for pulmonary coccidioidomycosis (Valley Fever)

INDICATION AND USAGE

SPHERUSOL® *(Coccidioides immitis)* Spherule-Derived Skin Test Antigen is indicated for the detection of delayed-type hypersensitivity to *Coccidioides immitis* in individuals with a history of pulmonary coccidioidomycosis. SPHERUSOL is approved for use in individuals 18-64 years of age.

- The use of SPHERUSOL to detect delayed-type hypersensitivity response in a general population with unknown exposure to *C. immitis* has not been evaluated.
- Persons with acute or disseminated coccidioidomycosis may not develop a delayed-type hypersensitivity response to SPHERUSOL.
- Persons with immunodeficiency and a history of coccidioidomycosis may not develop a delayed-type hypersensitivity response to SPHERUSOL.

WARNING:

The expected response to SPHERUSOL is a local area of inflammation at the site of the skin test. The reaction is usually dime to quarter size reaching maximum diameter between 24 and 48 hours. Larger accelerated reactions can occur, which may require treatment with local cold compresses and anti-inflammatory medication.

Systemic reactions can occur with skin test antigens and in certain individuals these reactions may be life-threatening or cause death. Emergency measures and personnel trained in their use should be immediately available. Patients should be observed for at least 20 minutes following the administration of a skin test.

SPHERUSOL should never be given intravenously.

Please see additional Important Safety Information on reverse side and the accompanying Full Prescribing Information.

NIELSEN BioSciences

Spher·u·sol®

(Coccidioides immitis)
Spherule-Derived Skin Test Antigen

SPHERUSOL: highly sensitive and specific for detecting skin test reactivity in clinical trials with patients who had a known history of pulmonary coccidioidomycosis[1]

Formulated without mercury-containing thimerosal

Sensitive

98% of clinical trial subjects from endemic areas in California and Arizona diagnosed with pulmonary coccidioidomycosis (n=54 enrolled), or Valley Fever, tested positive with SPHERUSOL (skin test response ≥5 mm)[1]

Specific

98% of clinical trial subjects from a nonendemic area of the U.S. without serologic evidence of coccidioidomycosis (n=60 enrolled), **tested negative** with SPHERUSOL (skin test responses <5 mm). **90%** of subjects with at least one positive control (candida or trichophyton) tested negative with SPHERUSOL[1]

0% cross-reactivity in clinical trial subjects diagnosed with another fungal pneumonia (histoplasmosis) caused by *Histoplasma capsulatum* (n=12 enrolled)[1]

IMPORTANT SAFETY INFORMATION

Contraindications

Severe allergic reaction (e.g., anaphylaxis) to SPHERUSOL® *(Coccidioides immitis)* Spherule-Derived Skin Test Antigen, or any component of SPHERUSOL or history of allergic reaction to other coccidioidins.

Warnings and Precautions

Acute hypersensitivity reactions and anaphylaxis have occurred following the administration of other skin test antigens and may occur in individuals following the administration of SPHERUSOL.

Patients receiving beta-blocking drugs may be refractive to the usual dose of epinephrine in cases of hypersensitivity.

Any condition or agent that impairs or attenuates delayed-type hypersensitivity reactions, including infections and use of immunosuppressive drugs, can potentially cause a false negative reaction to SPHERUSOL.

Adverse Reactions

The most commonly reported local adverse reactions were itching and swelling (>75%) and pain (>15%) within 7 days of administration.

Drug Interactions

Corticosteroids and immunosuppressive agents may suppress the response to the skin test.

Use in Specific Populations

The safety and effectiveness of SPHERUSOL have not been established in pregnant and nursing women, the pediatric population, or individuals >65 years of age.

This Important Safety Information does not contain all the information needed to use SPHERUSOL safely and effectively.

Please see the accompanying Full Prescribing Information for additional Important Safety Information.

Reference: 1. SPHERUSOL [package insert]. San Diego, CA: Nielsen BioSciences; July 2011.

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