STAPHYLOCOCCUS AUREUS PHAGE LYSATE
Staphage Lysate (SPL)®

for staphylococcal infections and staphylococcal hypersensitivity

Description

Staphylococcus Aureus Phage Lysate — Staphage Lysate (SPL)®— is a bacteriologically sterile staphylococcal vaccine containing the components of *S. aureus,* a bacteriophage, and some culture medium ingredients (sodium chloride and ultrafiltered beef heart infusion broth) in solution.

SPL is prepared by lysing cultures of *S. aureus,* Cowan Serologic Types I & III, with a polyvalent staphylococcus bacteriophage. Bacteriologic sterility is achieved by ultrafiltration. No chemical preservatives or inactivants are used in its preparation.

SPL is standardized on the basis of bacterial cell count before phage lysis. Each milliliter contains: 120-180 million colony-forming unit equivalents of *S. aureus* and at least 100 million staphylococcus bacteriophage plaque-forming units.

Clinical Pharmacology

Under experimental conditions, *S. aureus* or its cellular components induces cell-mediated immunity.[1]

In vitro, SPL has been shown to stimulate lymphocyte responses in both T-and B-cell subpopulations in the blood of normal human subjects.

In canine pyoderma studies, SPL has been used to treat and prevent recurrent skin infections.

These findings support the interpretation that SPL in staphylococcal-sensitized subjects acts as an immunopotentiator of cell-mediated immunity.

Animal Pharmacology

An increased capability of macrophages to inactivate staphylococci has been demonstrated in laboratory animals following SPL treatment.

SPL also has been shown to act as an immunomodulator.

Indications and Usage

SPL is indicated for the treatment of canine pyoderma and related staphylococcal hypersensitivity, or polymicrobial skin infections with a staphylococcal component.[2-9]

The use of SPL has not been shown to affect adversely other treatment modalities, although the concomitant use of systemic corticosteroids is not advised. Abnormal thyroid conditions should be corrected before beginning therapy. The concomitant use of antibiotics may be beneficial.

Contraindications

There are no known contraindications to the use of SPL except that in highly allergic patients reduced desensitizing doses may be indicated.

Precautions

> SPL does not contain a preservative; therefore, it must be handled aseptically. Do not use if it becomes cloudy. (This would indicate contamination.) Use entire contents when first opened.

General—A separate, sterile syringe and needle should be used for each individual, and aseptic technique must be used in removing doses from either the 1-mL ampules or the 10-mL vials.

Caution should be exercised when administering SPL to highly allergic patients (or those predisposed to allergy). See under *Dosage and Administration.*

In common with all antigens employed to stimulate the production of antibodies that are protective in the event of subsequent disease, SPL presents the remote potential of host sensitization to staphylococcal or bovine protein. Although anaphylaxis-type reactions are rare, the clinician must bear this possibility in mind. Epinephrine and atropine are antidotes.

Information for Clients—SPL may cause vaccine-type or site-of-injection reactions (see under *Adverse Reactions*) and, if excessive, these reactions may be lessened by dose reduction.

Pregnancy—Reproduction studies performed in rats and rabbits revealed no evidence of impaired fertility or harm to the fetus due to SPL.

Adverse Reactions

SPL may cause general vaccine-type reactions (i.e., malaise, fever, and/or chills). If excessive, these reactions may be lessened by dose reduction.

Transient reactions at the site of injection (i.e., redness, itching, and/or swelling) may occur in 2 to 3 hours and may last up to 3 days,

steadily decreasing. If excessive, these reactions may be lessened by dose reduction.

Dosage and Administration

SPL is administered by subcutaneous injection. The severity of the infection and the response of the patient should be the guiding factors in adjusting the dosage regimen.

All highly allergic patients (or those predisposed to allergy) should first be skin-tested to assess their relative sensitivity to SPL.

Although the chance of allergic reactions is very small, the patient should be observed for 45 minutes to 1 hour for immediate and for 48 hours for delayed reactions. Allergic reactions you might observe include weakness, vomiting, diarrhea, severe itching, and fast breathing.

For chronic, recurrent, refractory, or deep-seated infections, it may be necessary to increase cautiously the frequency and/or the dose to achieve the desired therapeutic re sponse.

Following the initial injection, subsequent injections should avoid previous injection sites.

If an undue amount of local redness, itching, and/or swelling ensues, await a partial subsidence of the reactions, proceed with 1/2 the previous dose, and make incremental increases at longer intervals.

Staphylococcal Infections or Staphylococcal Hypersensitivity—

Allergic Patients

Skin Test—0.05 to 0.1 mL intradermally.

Therapy—Initially 0.2 mL subcutaneously, then incremental increases of 0.2 mL once a week to 1.0 mL (a total of 5 injections). When you reach 1.0 mL, continue weekly injections of 1.0 mL for approximately 10-12 weeks.

Nonallergic Patients[2]

Skin Test—Not required for nonallergic patients.

Therapy—0.5 mL subcutaneously 2 times a week for 10 to 12 weeks, then 0.5 mL to 1.0 mL every 1 or 2 weeks.

Concomitant antibiotic therapy is recommended for an initial 4- to 6-week period.

The maximum dose should be decreased in small dogs and can be increased cautiously, if necessary, in large dogs to 1.5 mL. This dose is continued until improvement is demonstrated, then the interval may be lengthened gradually to the longest interval that maintains adequate clinical control.

How Supplied

SPL (Serologic Types I & III) is supplied in:
1-mL ampules, boxes of 10.
10-mL multidose vials.

Storage—Store at 2-7°C (36-45°F). Do not freeze.

References

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3. Halliwell REW, Gorman NT. *Veterinary clinical immunology.* Philadelphia: Saunders, 1989:505.
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5. DeBoer DJ. Strategies for management of recurrent pyoderma in dogs. *Vet Clin N Am: Small Anim Prac* 1990; *20*(6):1509-24.
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8. Morales CA, Schultz KT, DeBoer DJ. Antistaphylococcal antibodies in dogs with recurrent staphylococcal pyoderma. *Vet Immunol Immunopathol 1994;*42:137-47.
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