Stafal®

antistaphylococcal bacteriophage

Stafal® is a dermal solution containing polyvalent phage particles, operating on a broad range of strains of *Staphylococcus aureus*, including MRSA strains. It is also shown to be effective for other species of the genus Staphylococcus..

Stafal is registered in the Slovak Republic.

In The Czech Republic Stafal is available under The Specific Treatment Program (SpLP) in Immuno Allergology, Otorhinolaryngology and Surgery.

Indikácia

Indication group

Immunopreparation

Indications

- Topical application in infections caused by staphylococcal strains in human and veterinary medicine in all forms of staphylococcal infections. It is used for the destruction of staphylococcal cells at the site of ongoing infection.
- Elimination of etiologic agens of staphylococcal infection in the foci of infections (e.g. purulent processes of the cutis, subcutis and adnexes) and potential reservoirs (particularly in the nasopharynx and secondary in intestinal and urinary tract).
- Complex treatment of chronic forms of staphylococcal infections (purulent affections, abscesses, fistulae,

infections affecting deeply located soft tissues), that prevents potential septic status.

- Prevention of the occurrence of superimposed pyogenic post-operative complications.

MEDICAL SPECIALIZATION	INDICATIONS OF STAFAL
DERMATOLOGY ALLERGOLOGY – IMMUNOLOGY	purulent processes of the cutis, subcutis and adnexes (pyoderma, abscesses, acne, furuncle, carbuncle, sores and the like) manifestations of staphylococcal infections (skin or respiratory) – alone or in combination with allergen immunotherapy, possibly other treatments.
INFECTOLOGY (NOSOCOMIAL DISEASES)	MRSA in hospitals
SURGERY	Diagnosis based on infections caused by staphylococcal strains (osteomyelitis, prevention of superponed pyogenic postoperative complications, diabetic leg, infection of deeply located soft-tissues, prevention of sepsis, etc.). A secondary effect of Stafal to remote staphylococcal bearings (intestinal and urinary tract).
VETERINARY MEDECINE	All forms of staphylococcal infections.
OTORHINOLARYNGOLOGY	Acute, recurrent and chronic infections caused by staphylococcal strains, including MRSA, in particular: • Acute and chronic rhinitis • Acute and subacute sinusitis • Folliculitis and furunculosis of the nasal entrance • Impetigo of the external nose and nasal entrance • Recurrent external otitis • Chronic suppurative otitis media • Eradication of carriership of staphylococcus before surgical intervention in combination with antibiotic therapy

Contraindications

Hypersensitivity to some component of the preparation.

Interactions

No interactions have been observed

Adverse effects

Burning in the site of application, rarely.

- **Overdose**
  Unknown
- **Pregnancy and lactation**
  During pregnancy and breast feeding the administration of the preparation is at the attending physician's discretion. No adverse effect is assumed in the topical application of the preparation.

Stafal® and MRSA/VRSA

The discovery/appearance of pathogenic bacteria that are resistant to most antibiotics, is becoming a problem of modern medicine. Currently, there is increasing interest in research of the period before the discovery of antibiotics, when the use of bacteriophages as antimicrobial agents, was under the consideration, within the so-called phage therapy.

MRSA

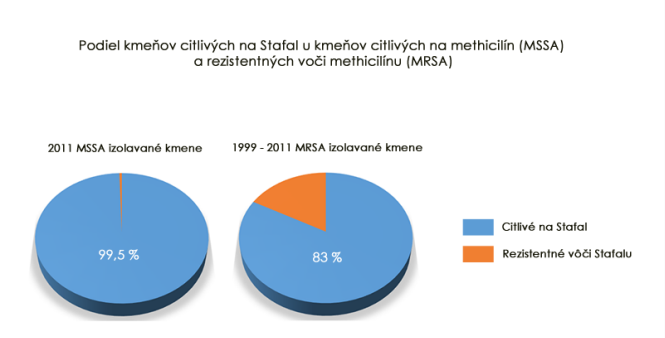
Methicillin-resistant *Staphylococcus aureus* (MRSA), is resistant to most antibiotics currently available. It occurs in hospitals and healthcare facilities providing acute and long-term care. It causes serious, often life-threatening complications of the underlying disease.

- Severe global clinical and economic problem
- Resistant to many antibiotics
- Infections caused by MRSA due to limited opportunities for antimicrobial therapy associated with high mortality and high costs
- Still responding to the so called last line antibiotics vancomycin and teicoplanin

In 2012, within the EU there was on average 17.8% of invasive isolates of MRSA, in Slovakia it was up to 21.7%. The ability to kill MRSA is one of the most important properties of staphylococcal lytic phages. Staphylococcal bacteriophage is a highly effective both in the treatment and prevention of MRSA.

Proven effectiveness of Stafal ® to 85% of MRSA strains!

The proportion of sensitive strains to Stafal in sensitive strains to methicillin (MSSA) and methicillin-resistant (of MRSA)



The sensitivity of of MRSA to various ba

PHAGE	STAFAL®	PYO BACTERIOPHAGUM	INTESTI BACTERIOPHAGUM
% of sensitive strains	**83**	73	72

Administration

Administration

Usually it is applied twice a day according to clinical findings.

- Disinfection of wounds by aggressive preparations
  – Alcohol, iodine preparations or H_2O_2 reduce the activity of Stafal®
  – Suitable preparations are Dermacyn or Prontosan
- Treatment of pressure ulcers/decubiti, diabetic leg, ulcerations
  – After application of Stafal® at the base of the defect cover by biofilm (Suprasorb, etc.).
  – Ensuring the optimal amount and efficiency. Radius of 1 cm covered with indifferent paste.
- Acne treatment
  – Apply daily after basic cleansing the skin until the regression of manifestations.

Forms of application/administration

- Lavaging
- Compressing (application of tampons steeped in STAFAL®)
- Spraying
- Nasal drops

Development

Development and production of a liquid and lyophilized form

Preparation of phage preparations in laboratory conditions was carried out already in the 70's of the last century, when the gradual application in the treatment of staphylococcal infections began. Based on a close cooperation with the Institute of Biophysics, Academy of Sciences in Brno, where the development of phage medicinal products was carried out by Dr. George Pillich and his colleagues, the manufacturing of Stafal at a greater scale was established/implemented in the Constitution of serums and vaccines already 30 years ago. Subsequently, the preparation was successfully used in over 70 clinical cases in the former Czechoslovakia.

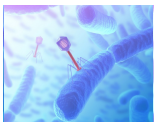
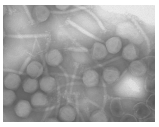
- **Commencement of production**
  In 1983, the production of Stafal® began in The Institute of Serums and Vaccines, Prague. Clinical trials were carried out in the years 1983-1984. The registration of the preparation took place in 1989 following the completion of clinical trials.
- **Reducing the cost of a treatment**
  Doctors, engaged in a treatment by Stafalo®, considered this treatment to be highly satisfactory
  and effective. Financial expenses of the fagotherapy of

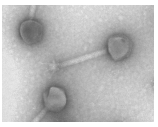
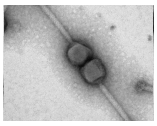
staphylococcal diseases were on average 5 times lower compared to the cost of antibiotic treatment.

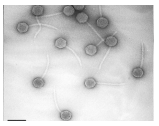
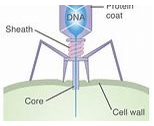
Currently, the liquid Stafal is registered in Slovakia as a medicinal preparation by Bohemia Pharmaceuticals.

In a cooperation with Masaryk University in Brno an ongoing development of a more stable lyophilized powder form has been carried out. In contrast to the liquid form it has the minimal expiration of 30 months.

Images

Výzkumní projekt společnosti Bohemia Pharmaceuticals, s.r.o.: Výzkum a vývoj nové vakcíny proti černému kašli. byl financován se zdrojů Evropských strukturálních fondů.

MINISTERSTVO PRŮMYSLU A OBCHODU
Výzkum a vývoj nové vakcíny proti černému kašli

Ministerstvo průmyslu a obchodu České republiky sekce fondů EU výzkumu a vývoje - Řídici orgán OPPIK

EVROPSKÁ ÚNIE
Evropský fond pro regionální rozvoj
OP Podnikání a inovace pro konkurenceschopnost