Treatment for Malignant Pleural Effusion (MPE)

Key Features:

- Chest Tube Administration
- Controlled Particle Size
- Gamma Irradiated
- Packaged Sterile in a 100ml Glass Vial
- Single Use, 5 gram Dosage

Sterile Talc Powder™ is indicated for use as a sclerosing agent to decrease the recurrence of MPE in symptomatic patients. A cost-effective treatment for MPE, Sterile Talc Powder™ provides uniform, consistent and clean administration via chest tube.

Studies1-5 demonstrate that talc, administered intrapleurally via chest tube, has a high success rate in treating MPE, relieving symptoms and decreasing the recurrence of pleural effusion.

Please see full prescribing information on the adjacent page.

To place an order for Product #1690, Sterile Talc Powder, please contact Bryan Corporation at:

Toll Free: 800.343.7711
Fax: 781.935.7602
Email: sales@bryancorp.com
www.bryancorp.com

4 Ong KC et al. Respirrology 2000; 5:99-103
Sterile Talc Powder is a sclerosing agent intended for intrapleural administration to control intrapleural effusions. It is a fine powder composed of hydrated magnesium silicate, the empirical formula of talc is Mg3(Si4O10)(OH)2 with a molecular weight of 378.3. Associated naturally occurring minerals include chlorite (hydrated aluminum magnesium silicate), dolomite (calcium and magnesium carbonate), calcite (calcium carbonate) and quartz. Talc is practically insoluble in water and in dilute solutions of acids and alkali hydroxides. The finished product has been sterilized by gamma irradiation.

**CLINICAL PHARMACOLOGY**

**Mechanism of Action**

The therapeutic action of talc instilled into the pleural cavity is believed to result from induction of an inflammatory reaction. This reaction promotes adherence of the visceral and parietal pleura, obliterating the pleural space and preventing reaccumulation of pleural fluid. The extent of systemic absorption of talc after intrapleural administration has not been adequately studied. Systemic exposure could be affected by the integrity of the pleural surface, and therefore could be increased if talc is administered immediately following lung resection or biopsy. Systemic exposure could be affected by the integrity of the pleural surface, and therefore could be increased if talc is administered immediately following lung resection or biopsy.

**CLINICAL STUDIES**

The data demonstrating safety and efficacy of talc slurry administered via chest tube for the treatment of patients with malignant pleural effusions are from the published medical literature. The following prospective, randomized studies were designed to evaluate the risk of recurrence of malignant pleural effusions in patients with a variety of solid tumors. The studies compared talc slurry, instilled into the pleural cavity via chest tube, versus a concurrent control. In all studies, after maximal drainage of the pleural effusion, the investigator administered talc slurry via chest tube. Chest films documented response (defined as lack of recurrence of fluid for a period of time). Studies differed on the timing of the efficacy assessment. Zimmer et al. did not specify the time required evaluations. On et al. specified the assessment at one month. Sorensen et al. specified the assessment at 3.4 months. The remaining studies assessed response at the completion of the follow-up period.

**REFERENCE**

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<th>Reference</th>
<th>Treatment</th>
<th>Response Rate: p value</th>
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<tr>
<td>Sorensen et al.</td>
<td>Talc Slurry 10g/250ml NS vs. Chest tube drainage alone</td>
<td>100% (9/9) vs. 58% (7/12)</td>
<td>64% (8/14) vs. 41% (7/17)</td>
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<td>Noppen et al.</td>
<td>Talc Slurry 5g/50ml NS vs. Bleomycin 1mg/kg/50ml NS</td>
<td>71% (9/14) vs. 75% (8/12)</td>
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<td>Zimmer PV et al.</td>
<td>Talc Slurry 5g/50ml NS vs. Bleomycin 10/600U/50ml NS</td>
<td>80% (17/10) vs. 75% (17/10)</td>
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<td>Ong KC et al.</td>
<td>Talc Slurry 5g/50ml NS vs. Bleomycin 10/600U/50ml NS</td>
<td>86% (16/10) vs. 70% (10/14)</td>
<td>86% (14/24) vs. 93% (14/25)</td>
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<tr>
<td>Yim AP et al.</td>
<td>Talc Slurry 5g/50ml NS vs. Idiotaxan 1% 10ml vs. Talc Insufflation 5s powder</td>
<td>90% (20/22) vs. 96% (22/23)</td>
<td>90% (20/22) vs. 96% (22/23)</td>
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**STORAGE AND DISTRIBUTION**

Sterile Talc Powder is supplied in a 100 ml brown glass bottle containing 5 g of Sterile Talc Powder. Each brown bottle contains 5 g of Sterile Talc Powder. To dispense the contents:

1. Using a 16 gauge needle attached to a 40 ml LuerLok syringe, measure and draw up 50 ml of Sodium Chloride Injection, USP, Vent the talc bottle using a needle. Slowly inject the 50 ml of Sodium Chloride Injection, USP into the bottle. For doses more than 5, repeat this procedure with a second bottle.

2. Swirl the bottle(s) to disperse the talc powder and continue swirling to avoid settling of the talc in the slurry.

Each bottle will contain 5 g Sterile Talc Powder dispersed in 50 ml of Sodium Chloride Injection, USP. To prepare the talc slurry:

1. Divide the content of each bottle into two 60 ml irrigation syringes by withdrawing 30 ml of each syringe.
2. Prepare the talc slurry using aseptic technique in an appropriate laminar flow hood. Remove talc container from packaging. Remove protective flip-off seal.


**PRECAUTIONS**

1. For intrapleural administration. The possibility of the future diagnostic and therapeutic procedures involving the hemithorax to be treated must be considered prior to administering Sterile Talc Powder. Sclerosis of the pleural space may preclude subsequent diagnostic procedures of the pleura on the treated side. Talo sclerosis may complicate or preclude future intrapleural surgical resection, including pneumonectomy for transplantation purposes.

2. Use in potentially curable disease: Talc has no known antineoplastic activity and should not be used alone for potentially curable malignancies where systemic therapy would be more appropriate, e.g., a malignant effusion secondary to a potentially curable lymphoma.

3. Pulmonary complications: Acute Pneumonitis and Acute Respiratory Distress Syndrome (ARDS) have been reported in association with intrapleural talc administration. The three cases of ARDS have occurred after treatment with a relatively large talc dose (10 g) administered via intrapleural chest tube instillation. One patient died one month post treatment and two patients recovered without further sequelae.

**CONTRAINdications**

None known.

**WARNINGS**

None.

**ADVERSE REACTIONS**

Intrathoracic administration of talc slurry has been described in medical literature reports involving more than 2000 patients. Patients with malignant pleural effusions were treated with talc via poudrage or slurry. In general, with respect to reported adverse experiences, it is difficult to distinguish the effects of talc from the effects of the procedures(s) associated with its administration. The most often reported adverse experiences to intrapleurally-administered talc were fever and pain.

**Infection**

Complications reported include empyema. Respiratory:

Complications reported include hypoxemia, dyspnea, unilateral pulmonary edema, pneumo- nia, ARDS, atelectasis, fibrosis, hemoptysis and pulmonary infiltrates. Cardiovascular:

Complications reported included tachycardia, myocardial infarction, hypertension, hypovolemia and asystolic arrest.

**Delivery Procedure**

Adverse reactions due to the delivery procedure and the chest tube may include: pain, infection at the site of thoracostomy or thoracoscopy, localized bleeding, and subcutaneous emphysema. Chronic Toxicity:

Since patients in clinical studies had a limited life expectancy, data on chronic toxicity are limited.

**OVERDOSAGE**

No definite relationship between dose and toxicity has been established. Excessive talc may be partially removed with saline lavage.

**DOSE AND ADMINISTRATION**

Sterile Talc Powder should be administered after adequate drainage of the effusion. The success of the pleurodesis appears to be related to the completeness of the drainage of the pleural fluid, as well as the full re-expansion of the lung, both of which will promote symphysis of the pleural surfaces. Because animal reproduction studies are not always predictive of human response, this drug should not be used in pregnant women. Neonatal use has not been sufficiently studied to determine its effect on the intrauterine development of the fetus.

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**HOW SUPPLIED**

NDC 63256-200-05 Sterile Talc Powder is supplied in a 100 ml brown glass bottle containing 5 g of talc. Sterile Talc Powder is supplied in a 100 ml brown glass bottle containing 5 g of talc. The sterile bottle is closed with a gray stopper and covered with a flip-off seal. Storage: Store at Room Temperature (18-25°C). Protect against sunlight.

**DISTRIBUTED BY:** Bryan Corporation, Woburn, MA 01801