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.

Studies\textsuperscript{1-5} 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

\textsuperscript{1} Sorensen et al. Eur J Respir Dis. 1984; 65(2): 131-5
\textsuperscript{2} Noppen et al. Acta Clin Belg 1997; 52(4):298-62
\textsuperscript{3} Zimmer PW et al. Chest 1997; 112(2):430-434
\textsuperscript{4} Ong KC et al. Respirology 2000; 5:99-103
Sterile Talc Powder

DESCRIPTION
Sterile Talc Powder is a sclerosing agent intended for intrapleural administration supplied in a single use 100 ml brown glass bottle, sealed with a gray, 20 mm stopper and covered with a flip-off seal. Each bottle contains a minimum of 5.0 g of Talc USP(Ultra 2000 Talc), either white or off-white to light gray, asbestos-free and brukner free grade of talc of controlled particle size. The composition of the talc is > 95% talc as hydrated magnesium silicate. The empirical formula of talc is Mg3Si4O10(OH)2 with a molecular weight of 397.3. Associated naturally occurring minerals include chloride (hydrated aluminum and 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.

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 offered on the timing of the efficacy assessment. Sorenson et al did not specify the time required evaluations. Ong et al specified the assessment at 1 month. Sorenson et al specified the assessment at 3-4 months. The remaining studies assessed response at the completion of the follow-up period.

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 pleurodose or slurry. In general, with respect to reported adverse experiences, it is difficult to distinguish the effects of talc from the effects of the procedure(s) associated with its administration. The most often reported adverse experiences to intrapleurally-administered talc were wound and pain.

Infection: Complications reported included empyema.

Respiratory: Complications reported included hypoxemia, dyspnea, unilateral pulmonary edema, pneumo-

Cardiovascular: Complications reported included tachycardia, myocardial infarction, hypotension, hypovolemic and anoxic arrest.

DRUG INTERACTIONS

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.

The recommended dose is 5 g, dispersed in 50-100 ml Sodium Chloride Injection, USP. Although the optimal dose for effective pleurodesis is unclear, 5 g was the dose most frequently reported in the published literature.

Talc Preparation
Prepare the talc slurry using aspecific technique in an appropriate laminar flow hood. Remove talc container from packaging. Remove protective flip-off seal.

Each bottle contains 5 g of Sterile Talc Powder. To dispense the contents:

1. Using a 16 gauge needle attached to a 60 ml Luer-Lok syringe, mix and draw up 50 ml of Sodium Chloride Injection, USP.

2. With the syringe needle attached to a 10 ml air headspace syringe, attach the needle to the bottle. Slowly inject the 50 ml of Sodium Chloride Injection, USP into the bottle. For doses more than 5 g, repeat this procedure with a second bottle. After the 10 ml of slurry has been injected, remove the needle.

3. To avoid settling, invert the bottle gently 10 times after each 10 ml of injection. If the talc has settled, gently agitate the bottle before each injection.

4. After approximately 15 minutes, the slurry will be completely combined. Use the slurry immediately.

INDICATIONS AND USAGE

Sterile Talc Powder, administered intrapleurally via chest tube, is indicated as a sclerosing agent to decrease the recurrence of malignant pleural effusions in symptomatic patients.

CONTRAINdications

None known

WARNINGS

None

PRECAUTIONS

1. Future procedures: The possibility of the future diagnostic and therapeutic procedures involving the hemithorax 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. Talc sclerosis may complicate or preclude future ipsilateral lung resective surgery, 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. Three of the case reports 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.


DISTRIBUTED BY: Bryan Corporation, Woburn, MA 01801

STORAGE: Store at Room Temperature (19-25°C). Protect against sunlight.