Sclerosol® Intrapleural Aerosol is indicated for the prevention of recurrent MPE in symptomatic patients. A cost-effective treatment for MPE, Sclerosol provides uniform, consistent, rapid, and clean administration.

Studies\(^1\)\(^4\) demonstrate that talc, administered thorascopically, has a statistically high success rate in treating MPE, relieving symptoms and managing the pleural effusion.

Please see full prescribing information on the adjacent page.

To place an order for Product #1680, Sclerosol® Intrapleural Aerosol, please contact Bryan Corporation at:

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

\(^3\) Fentiman et al. Cancer, 1983; 52:737  
DESCRIPTION
Sclerosol® Intrapleural Aerosol (sterile talc powder 4 g) is a sclerosing agent for intrapleural administration supplied as a single-use, pressurized spray canister with two delivery tubes of 15 cm and 25 cm in length. Each canister contains 4 g of talc, either white or off-white to light grey, asbestos-free, and brucite-free grade of talc of controlled granulometry. The composition of the talc is ≥ 95% talc as hydrated magnesium silicate. The empirical formula of Mg3 Si4 O10 (OH)2 with molecular weight of 379.3. Associated naturally occurring minerals include chlorite (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 canister and delivery tubes have been sterilized by gamma irradiation. The aerosol propellant contained in Sclerosol® Intrapleural Aerosol is dichlorodifluoromethane (CFC-12) with 36 g present per canister. The canister delivers 0.4 g of talc per second through the valve and the product contains no other excipients.

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 to the parietal pleura, obliterating the pleural space and preventing reaccumulation of pleural fluid. The extent of talc systemically absorbed after intrapleural administration has not been adequately studied. Systemic exposure could be affected by the integrity of the visceral pleura, 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 in the treatment of malignant pleural effusions are derived from the published medical literature. The following four trials were prospective, randomized studies of talc vs. a concurrent control, and provide sufficient detail for evaluation, including a clear, readily defined definition of response (no fluid reaccumulation by chest roentgenogram at one month or greater) and information allowing an analysis of all patients randomized. Talc was statistically significantly superior to the control arms in evaluable patients across the studies.

INDICATIONS AND USAGE
Sclerosol® Intrapleural Aerosol, administered by aerosol during thoracoscopy or open thoracotomy, is indicated to prevent recurrence of malignant pleural effusions in symptomatic patients.

CONTRAINDICATIONS
None known.

WARNINGS
None.

PRECAUTIONS
General:
1) Future procedures. The possibility of future diagnostic and therapeutic procedures involving the hemithorax to be treated must be considered prior to administering Sclerosol® Intrapleural Aerosol. Sclerosol® Intrapleural Aerosol (sterile talc powder) contains 4 g of talc suspended in 26 g of inert propellant in a single-use aluminum canister. The canister is fitted with a continuous spray valve which delivers approximately 0.4 g of talc per second. This canister, attached to an actuator button, and two delivery tubes of 15 cm and 25 cm length, are supplied in a sterile, flexible plastic peel pack.

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

3) Potential pulmonary complications. Acute pneumonitis or acute respiratory distress syndrome (ARDS) have been reported in association with intrapleural talc administration. Whether these were causally related to talc is unclear. In none of the reported cases was talc applied thoroscopically or by insufflation. Three of four case reports of ARDS have occurred after treatment with 10 g of talc administered via an intrapleural chest tube instillation. One patient died one month post treatment and two patients recovered without further sequelae.

4) Contents under pressure. The contents of the Sclerosol® Intrapleural Aerosol (sterile talc powder) canister are under pressure. The canister must not be punctured and should not be used or stored near heat or open flame.

Drug Interactions: It is not known whether the effectiveness of a second sclerosing agent after prior talc pleurodesis would be diminished by the absorptive properties of talc.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies on the carcinogenicity of talc have been performed using non-standard designs, which prevent firm conclusions on its carcinogenicity. With single intrapleural administration a single dose at 32 mg and observation for at least 6 months, 4 weekly doses administered intrapleurally at 25 mg/dose to rats with observation for at least 84 weeks, tumor incidence was not increased. In these studies, the talc and its asbestos content were not characterised. Genotoxicity was assessed in cultures of rat lung, in vitro, using unchelated DNA synthesis (UDS) and sister chromatid exchanges (SCEs). None of the talc samples (which were asbestos free) enhanced UDS or SCEs in treated cultures. No information is available on impartment of fertility in animals by talc.

Pregnancy: Pregnancy category B. An oral administration study has been performed in the rabbit at 900 mg/kg, approximately 5-fold higher than the human dose on mg/m² basis, and has revealed no evidence of teratogenicity due to talc. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless it is clearly needed.

PEDIATRIC USE:
The safety and efficacy of Sclerosol® Intrapleural Aerosol (sterile talc powder) in pediatric patients has not been established.

INDICATIONS:
The mean and median ages of patients treated with talc in the clinical studies table were 50-62 years. No analyses to specifically evaluate the safety and efficacy in the geriatric population have been reported.

ADVERSE REACTIONS
Talc administration has been described in more than 1500 patients reported in the medical literature. 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 tumors associated with its administration. The most reported adverse experiences following talc instillation are fever and pain. Almost all of the cases of fever, and over half of the cases of pain, were in patients who received diagnostic biopsies at the time of talc administration.

Infections: Empyema was a rare complication of talc administration and/or the procedure. Biopsies had been obtained prior to onset in over half the reported cases.

Respiratory: Rare instances of pneumonia, ARDS, dyspnea, bronchopleural fistula, hemoptysis, and pulmonary emboli have been reported.

Cardiovascular: Tachycardia, myocardial infarction, hypotension, hypovolemia, and asymptotic arrest associated with surgery and/or anesthesia have been rarely reported.

OVERDOSAGE
Overdoses have not been reported. (See PRECAUTIONS: 3) Potential pulmonary complications.

DOSAGE AND ADMINISTRATION
Sclerosol® Intrapleural Aerosol (sterile talc powder) is administered after adequate drainage of the effusion. It has been suggested that success of the pleurodesis is related to the completeness of the drainage of the pleural fluid, as well as full reexpansion of the lung, both of which will promote symphysis of the pleural surfaces. The usual dosage of Sclerosol® Intrapleural Aerosol (sterile talc powder) is a single 4-8 g dose delivered intrapleurally from the spray canister (1-2 cans), which delivers talc at a rate of 0.4 g per second.

ADMINISTRATION PROCEDURE
Shake canister well before usage. Remove protective cap and securely attach actuator button with its delivery tube (either 15 cm or 25 cm) to the valve stem of canister. Insert delivery tube through pleural trocar, taking care not to place the distal end of the delivery tube adjacent to the lung parenchyma or directly against the chest wall. While firmly holding the delivery tube and pleural trocar together in one hand, gently apply pressure to the actuator button on the canister. Sclerosol® Intrapleural Aerosol is not delivered by metered dose, but depends on the extent and duration of manual compression of the actuator button on the canister. The distal end of the delivery tube should be pointed in several different directions, while short bursts are administered in order to distribute the talc powder evenly and extensively on all visceral and parietal pleural surfaces. For optimal distribution, always hold the Sclerosol® Intrapleural Aerosol (sterile talc powder) canister in the upright position. After application, discard the canister and delivery tube. The duration of chest tube drainage following talc sclerosis is dictated by the clinical situation.

HOW SUPPLIED
NDC 63256-0100-30: Sclerosol® Intrapleural Aerosol (sterile talc powder) contains 4 g of talc suspended in 26 g of inert propellant in a single-use canister with a continuous spray valve which delivers approximately 0.4 g of talc per second. This canister, attached to an actuator button, and two delivery tubes of 15 cm and 25 cm length, are supplied in a sterile, flexible plastic peel pack.

STORAGE: Warning: Contents under pressure. Do not puncture or incinerate container. Store between 59°F - 86°F (15°C - 30°C). Protect against sunlight and do not expose to a temperature above 120°F (49°C), or the canister may rupture. Avoid freezing. Shake well before using.

Note: The indentent statement below is required by the Federal Government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFCs).

WARNING: Contains CFC-12, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

Distributed by: BRYAN CORPORATION, WOBURN, MA 01801.