Composition
Viarex Aerosol is a metered-dose aerosol unit, containing a suspension of microcrystalline beclomethasone dipropionate in inert liquefied propellants with oleic acid as a dispersing agent.

Each metered dose (actuation) provides 50 µg of beclomethasone dipropionate per inhalation with specially designed oral and nasal adaptors. Each canister of Viarex Aerosol provides 100 metered doses, sufficient for 15 days of therapy for most patients, or 200 metered doses, sufficient for 30 days of oral inhalation or intranasal use.

Inactive ingredients: oleic acid, trichlorofluromethane and dichlorodifluoromethane.

Properties
Beclomethasone dipropionate, a corticosteroid, demonstrates anti-inflammatory properties in the respiratory tract at doses which are not systemically active.

Indications
A. Oral
Viarex Aerosol is indicated for the management of asthmatic patients, particularly those who have been dependent upon either systemically administered corticosteroids or corticotrophin (ACTH) and non-corticosteroid-dependent patients inadequately controlled on other drug regimens.

Oral inhalation of Viarex Aerosol is particularly indicated in the following patients:
1. Asthmatic patients requiring long-term maintenance therapy.
2. Severe asthmatic patients who are dependent on systemic corticosteroids or ACTH.
3. Asthmatic patients who are receiving intermittent courses of systemic corticosteroids.
4. Asthmatic patients whose symptoms have become less responsive to bronchodilators and require progressively higher dosages for relief.
5. Asthmatic patients for whom bronchodilator therapy is relatively contraindicated such as cardiac patients.
6. Asthmatic patients whose symptoms are not controlled adequately by combination therapy (bronchodilators with dl-sodium cromoglycate).
7. Children with severe asthma. Effective control of symptoms has been achieved without the retardation of growth commonly associated with systemic corticosteroid administration. Resumption of growth has been reported in children transferred from systemic corticosteroids to beclomethasone dipropionate therapy.

In the management of chronic obstructive bronchitis, Viarex Aerosol may be effective in candidates suitable for transfer to an inhaled corticosteroid when the severity and presence of an inflammatory component indicate the necessity for systemic corticosteroids. Patients who are already maintaining a satisfactory response to systemically active corticosteroids for chronic obstructive bronchitis (corticosteroid dependent) should be transferred gradually to Viarex Aerosol (See Dosage and Administration).

Those patients who have not received systemic corticosteroid therapy for chronic obstructive bronchitis but whose condition is severe enough for such therapy may be treated with Viarex Aerosol alone.

Patients with chronic obstructive bronchitis who are receiving Viarex Aerosol may also require supportive therapy in the form of short courses of systemically active corticosteroids and antibiotics for infection, as well as bronchodilators for bronchospasm and mucolytics for excessive mucus.

B. Intranasal
Viarex Aerosol is indicated as an intranasal spray for the relief of symptoms of seasonal or perennial allergic rhinitis and vasomotor rhinitis. It may also be used as adjunctive therapy in the medical treatment of nasal polyps.
**Contraindications**
Viarex Aerosol is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required and in patients with known hypersensitivity to any of the ingredients of this preparation.

**Side Effects**

**Oral:**
Deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to aerosol beclomethasone dipropionate. Reduction of early morning plasma cortisol has been reported in adult patients who received 1,600 µg daily doses of oral beclomethasone dipropionate inhaler for one month. Systemic corticosteroid side effects have been reported rarely with Viarex Aerosol. If recommended doses are exceeded or individuals are particularly sensitive, symptoms of hypercorticism could occur. If such symptoms occur, Viarex Aerosol should be discontinued slowly, consistent with accepted procedures for discontinuing oral corticosteroid therapy. Hoarseness and dry mouth have occurred in a few patients. Immediate and delayed hypersensitivity reactions, bronchospasm, rash, urticaria, angioedema and localized infection with Candida albicans or Aspergillus niger in the mouth, throat, larynx, bronchus and esophagus have been reported.

**Intranasal:** Reported side effects include irritation and burning in the nose, cough, transient episodes of sneezing and transient episodes of epistaxis or blood-stained nasal secretions. Localized infections of the nose and pharynx with Candida albicans, ulceration of the nasal mucosa, nasal septum perforation, increased intraocular pressure and immediate and delayed hypersensitivity reactions including urticaria, angioedema, rash and bronchospasm have occurred rarely.

**Precautions**
Frequency of clinically apparent localized infection with Candida albicans or Aspergillus niger is low. However, these infections may require treatment with appropriate antifungal therapy or discontinuance of oral Viarex Aerosol treatment. Oral Viarex Aerosol is not to be regarded as a bronchodilator and is not indicated for rapid relief of bronchospasm. Patients should be instructed to contact their physician immediately when asthmatic episodes are not responsive to bronchodilators during treatment with oral Viarex Aerosol. During such episodes, patients may require systemic corticosteroid therapy. No evidence supports the oral or intranasal administration of Viarex Aerosol in amounts greater than recommended doses. Transfer of patients from systemic corticosteroid therapy to oral or intranasal Viarex Aerosol may unmask pre-existing allergic conditions previously suppressed by systemic corticosteroid therapy. Long-term effects of beclomethasone dipropionate in human subjects are not completely known: in particular, the local effects of agent on development or immunologic processes in the mouth, pharynx, trachea and lung. Follow-up of patients treated with beclomethasone dipropionate for up to 10 years has shown no evidence of detrimental local structural or physiologic changes nor have any adverse systemic symptoms become apparent. Oral or intranasal Viarex Aerosol should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex. Pulmonary infiltrates with eosinophilia may occur in patients on oral Viarex Aerosol therapy. Although corticosteroid withdrawal effects are usually transient and not severe, severe and even fatal responses could occur because of adrenal insufficiency or because of exacerbation of asthma. Patients should be advised that Viarex Aerosol, when used in the treatment of asthma, does not provide rapid relief of breathing difficulties during an asthma attack. Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septal ulcers, nasal surgery or trauma should not use a nasal corticosteroid until heal-
ing has occurred. Safety and effectiveness for use in children less than 6 years of age have not been established.

Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs. This is of particular importance in children.

**Pregnancy and Lactation**
Beclomethasone dipropionate should be used in pregnant women, nursing mothers or women of child-bearing age only if the potential benefit justifies the potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be carefully observed for hypoadrenalism. If a decision is taken to administer Viarex Aerosol to nursing women, caution should be exercised.

**Overdosage**
When Viarex Aerosol is used at excessive doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may occur. If such symptoms do occur, the dosage should be decreased.

**Storage**
Contents are under pressure: Avoid exposure to direct sunlight, heat or open flame. Exposure to temperatures above 49ºC may cause bursting. Canister should never be punctured, broken or burned even if apparently empty. Keep out of reach of children.

**Dosage and Administration**
Do not exceed the recommended dosage. Shake canister well before each use.

*For oral inhalation:*
The usual recommended dosage is as follows: **Adults:** Two inhalations (each 50 µg) by mouth three or four times a day. In severe cases, dosage during initial therapy may be doubled (600-800 µg per day). When improvement occurs, the dosage should be adjusted according to response. **Children 6 to 12 years of age:** One or two inhalations (50 to 100 µg) two, three or four times a day, depending on age and response. For intranasal spray:
The usual dose for adults and children 6 years of age or over is one spray (50 µg) into each nostril two to four times daily. The therapeutic effects of intranasal Viarex Aerosol use, unlike decongestants, are not immediate. Relief from symptoms of rhinitis usually becomes apparent within a few days after the start of therapy. The maximum combined daily dosage should not exceed 20 metered dose applications (1 mg) for adults; and 10 metered dose applications (0.5 mg) for children 6 to 12 years of age.

Instructions to patients: The proper use and operation of the pressurized canister must be clearly understood by the patient. Physicians should emphasize to patients the need for regular oral or intranasal use of Viarex Aerosol.

*For Oral Inhalation:* The patient must breathe out, expelling as much air from the lungs as possible, and hold his breath while placing the mouthpiece in his mouth and grasping it with his teeth. The patient should then inhale deeply through the mouth while activating the spray mechanism and should try to hold his breath a few seconds before exhaling. Adults should repeat the procedure for a second inhalation. Patients should be advised that Viarex Aerosol is intended for treatment of asthma and it does not provide rapid relief of breathing difficulties during an asthma attack. If carefully instructed, children will learn quickly to keep the stream of mist clear of teeth and tongue, thereby assuring proper inhalation. Occlusion of the nostrils of very young children may be helpful to insure adequate inhalation. Rinsing the mouth after inhalation is advised to remove any medication. Patients receiving inhalation bronchodilators should be advised to use the
bronchodilator before Viarex Aerosol. After use of an aerosol bronchodilator, several minutes should elapse before use of Viarex Aerosol.

For Intranasal Spray: It is imperative that the nasal passages be clear before using Viarex Aerosol as an intranasal spray. This may be done simply by blowing the nose or by taking, when necessary other appropriate measures (such as nasal vasoconstrictor) as prescribed by the physician.

Management in Bronchial Asthma:
Patients Not Receiving Systemic Corticosteroids or ACTH - Administration of Viarex Aerosol may be initiated directly to patients who are not receiving systemic corticosteroids or ACTH. In patients who respond to Viarex Aerosol, an improvement in pulmonary function is usually apparent within one to four weeks.

Administration in Corticosteroid and ACTH-Dependent Patients
Since hypothalamic-pituitary-adrenal (HPA) axis suppression may be present in patients receiving systemic corticosteroid or ACTH, special care should be taken in transferring these patients to Viarex Aerosol therapy. Such suppression has been known to last for up to 12 months or longer. During the first week, Viarex Aerosol should be administered along with the patient’s maintenance dose of systemic corticosteroid.

Subsequently, Viarex Aerosol therapy should be maintained while the systemic corticosteroid is gradually reduced to a minimal dosage at a rate not to exceed 0.1 mg of betamethasone (or its equivalent) at intervals of one or two weeks, depending on the patient’s response. With ACTH dependent patients, the transfer should be made similarly reducing the ACTH dosage accordingly. The importance of a slow rate of withdrawal cannot be overemphasized. Some patients may experience symptoms of systematically active corticosteroid withdrawal despite the maintenance or improvement of pulmonary function and will require encouragement to continue Viarex Aerosol therapy. If evidence of adrenal insufficiency occurs, the systemic corticosteroid dose should be boosted temporarily and subsequent withdrawal should continue more slowly. During periods of stress or a severe asthmatic attack, transfer patients will require supplementary treatment with a short course of systemic corticosteroid which is gradually tapered as symptoms subside. It is recommended that such patients carry a supply of oral corticosteroids and a warning card indicating their need and recommended dosage of systemic corticosteroids during stressful periods. Periodic testing of adrenocortical function, particularly measurement of early morning plasma cortisol levels, should be performed.

Management with Intranasal Use:
Patients receiving systemic corticosteroid or ACTH - Special care should be taken in transferring these patients to intranasal use of Viarex Aerosol, as described above in Management of Bronchial Asthma in Corticosteroid and ACTH-Dependent Patients. Concomitant Use with Beclomethasone Dipropionate Inhaler and Nasal Spray. Viarex Aerosol may be used concomitantly with beclomethasone dipropionate inhaler or nasal spray in a total combined daily dose up to 1,000 µg in adults and 500 µg in children.

No evidence of adrenal suppression was seen with patients receiving concurrent administration of the recommended daily doses of both preparations.