Soprobec (beclometasone dipropionate) 50, 100, 200 or 250 micrograms per actuation pressurised inhalation solution. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Indications:** Soprobec is indicated for the maintenance treatment of asthma when the use of pressurised metered dose inhaler is appropriate. **Dosage and administration:** Soprobec is for inhalation use. Adjust starting dose of inhaled beclometasone dipropionate to severity of disease, then adjust until control is achieved and then titrate to the lowest dose at which effective control of asthma is maintained. Adults (including the elderly): usual starting dose is 200 micrograms twice daily. Severe cases may be increased to 600 to 800 micrograms daily. (Soprobec 250 only: usually 1000 micrograms daily, which may be increased to 2000 micrograms daily). Dose may be reduced when the patient's asthma has stabilised. The total daily dosage should be administered as 2 to 4 divided doses. The Volumatic™ spacer device must always be used when Soprobec is administered to adults and adolescents 16 years of age and older taking total daily doses ≥ 1000 micrograms. Children: usual starting dose is 100 micrograms twice daily. Depending on the severity of asthma, the daily dose may be increased up to 400 micrograms administered in 2 to 4 divided doses. Soprobec 200 and 250 is not recommended for children. Soprobec must always be used with the Volumatic™ spacer device when administered to children and adolescents 15 years of age and under, whatever dose has been prescribed. Patients with hepatic or renal impairment: No dosage adjustment needed Soprobec is for inhalation use. To ensure proper administration of the medicinal product, the patient should be shown how to use the inhaler correctly by a physician or other health professional. Correct use of the pressurised metered dose inhaler is essential in order that treatment is successful. The patient should be advised to read the Package Leaflet carefully and follow the instructions for use as given in the Leaflet. **Please refer to the SmPC for details of testing the inhaler and instructions for use**. Patients who find it difficult to co-ordinate actuation with inspiration of breath should be told to use a Volumatic™ spacer device to ensure proper administration of the product. Young children may find it difficult to use the inhaler properly and will require help. Using the inhaler with the Volumatic™ spacer device with a face mask may help in children under 5 years. Advise the patient to thoroughly rinse the mouth or gargle with water or brush the teeth immediately after using the inhaler. The patient should be told of the importance of cleaning the inhaler at least weekly to prevent any blockage and to carefully follow the instructions on cleaning the inhaler printed on the PIL. The inhaler must not be washed or put in water. The patient should be told also to refer to the PIL accompanying the Volumatic™ spacer device for the correct instructions on its use and cleaning. **Contraindications:** Hypersensitivity to norflurane (HFA-134a), ethanol anhydrous, glycerol or beclometasone dipropionate. **Warnings and precautions**: Patients should be properly instructed on the use of the inhaler to ensure that the drug reaches the target areas within the lungs. Patients should also be informed that Soprobec should be used on a regular basis, even when they are asymptomatic. Soprobec should not be used as the first treatment for asthma for treatment of acute asthma attacks patients. For such cases patients should be advised to have their rapid-acting bronchodilator available at all times. Treatment with Soprobec should not be stopped abruptly. If patients find the treatment ineffective medical attention must be sought. Increasing use of rescue bronchodilators indicates a worsening of the underlying condition and warrants a reassessment of the asthma therapy. Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should undergo urgent medical assessment. Systemic effects of inhaled corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. Possible systemic effects include Cushing's syndrome, cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained. It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled corticosteroids, if possible, to the lowest dose at which effective control of asthma is maintained. In addition, consideration should also be given to referring the patient to a paediatric respiratory specialist. Prolonged treatment with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Situations which could potentially trigger acute adrenal crisis, include trauma, surgery, infection or any rapid reduction in dosage. Presenting symptoms are typically vague and may include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, vomiting, hypotension, decreased level of consciousness, hypoglycaemia, and seizures. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. Care should be taken when transferring patients to Soprobec therapy, particularly if there is any reason to suppose that adrenal function is impaired from previous systemic steroid therapy. Patients transferring from oral to inhaled corticosteroids may remain at risk of impaired adrenal reserve for a considerable time. Patients who have required high dose emergency corticosteroid therapy in the past or have received prolonged treatment with high doses of inhaled corticosteroids may also be at risk. This possibility of residual impairment should always be borne in mind in emergency and elective situations likely to produce stress, and appropriate corticosteroid treatment must be considered. The extent of the adrenal impairment may require specialist advice before elective procedures.Patients weaned off oral steroids whose adrenocortical function is impaired should carry a steroid warning card indicating that they may need supplementary systemic steroids during periods of stress, e.g. worsening asthma attacks, chest infections, major intercurrent illness, surgery, trauma, etc. Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic drug. As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis. As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing, shortness of breath and cough after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Soprobec should be discontinued immediately, the patient assessed and, if necessary, alternative therapy institute. To reduce the risk of Candida infection, patients should be recommended to rinse their mouth properly after each drug administration. Special care is necessary in patients with viral, bacterial and fungal infections of the eye, mouth or respiratory tract. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for ophthalmologist evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Soprobec contains 7.47 mg of alcohol (ethanol) in each actuation which is equivalent to 13% w/w. **Interactions:** Theoretical potential for interaction of ethanol (excipient) in particularly sensitive patients taking disulfiram or metronidazole. Suppressive effect on adrenal function occurs with concomitant systemic or intranasal steroids. Caution and appropriate monitoring in CYP3A inhibitors (e.g. ritonavir, cobicistat). **Pregnancy and lactation:** There is no experience of the use of this product in pregnancy and lactation in humans. **Adverse reactions:** *Very common and common:* Oral candidiasis (of the mouth and throat), hoarseness, throat irritation. *Uncommon:* hypersensitivity reaction with the following manifestations: Rash, urticaria, pruritus, erythema. *Very rare:* oedema of the eyes, face, lips and throat, anaphylactic / anaphylactoid reactions, Cushing's syndrome, cushingoid features, adrenal suppression, growth retardation (in children and adolescents), bone density decreased, cataract, glaucoma, paradoxial bronchospasm, wheezing, dyspnoea, cough. *Unknown frequency:* Psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural disorders (predominantly in children), headache, vision blurred. Please consult the summary of product characteristics for a full list of adverse reactions. **Marketing authorization number:** PL 25258/0279. **Marketing Authorization Holder:** Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2B Draycott Avenue, Kenton, Middlesex, HA3 0BU, United Kingdom **Distributor:** As above. **Legal classification:** POM. Price: 50mcg £2.78, 100mcg £5.57, 200mcg £12.13, 250mcg £12.22. **Job code:** PP-UK-SOP-0116 **Date PI was drawn up:** Nov 2020

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk.
Adverse events should also be reported to medical_information@glenmarkpharma.com
or call 0800 458 0383

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