Kelhale Metered Dose Inhaler (beclometasone dipropionate)
Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Kelhale 50 microgram (µg); Kelhale 100 microgram (µg) beclometasone dipropionate (ex-valve) per actuation pressurised inhalation, solution. **INDICATIONS:** For prophylactic management of mild, moderate or severe asthma in adults over 18 years of age. **POSOLOGY AND ADMINISTRATION: For inhalation only. Adjust dose to the needs of patient. The recommended total daily dose of Kelhale is lower than for most other beclometasone dipropionate containing products. Kelhale must be used regularly to be effective, even when asymptomatic (see SmPC and patient information leaflet).** Recommended doses in adults 18 years and older: Mild asthma: 100 µg – 200 µg per day in two divided doses. Moderate asthma: 200 µg – 400 µg per day in two divided doses. Severe asthma: 400 µg – 800 µg per day in two divided doses. Patients on budesonide or fluticasone inhalers may be transferred to Kelhale. The maximum total daily dose is 800 µg per day in divided doses. **See the SmPC for further information on switching from budesonide, fluticasone, initiation and spacer use. CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **SPECIAL WARNINGS AND PRECAUTIONS:** Patients should be properly instructed on the use of their inhaler so that the drug reaches the target areas within the lungs. Kelhale should be used on a regular basis to be effective. Kelhale treatment should not be stopped abruptly. Patients with asthma are at risk of acute attacks and should have regular assessments of their asthma control, including pulmonary function tests. Kelhale should not be used to treat acute asthma symptoms for which a short-acting bronchodilator is required. Severe asthma exacerbations should be managed in the usual way. Severe asthma requires regular assessment. Patients should be advised to seek medical attention if peak flow falls, symptoms worsen or if the short-acting bronchodilator becomes less effective and increased inhalations are required. Withdrawal of systemic steroids should be gradual, starting about seven days after introduction of beclometasone dipropionate. When transferring a patient to inhaled steroid treatment, special care is necessary for the first few months of treatment until the HPA system has sufficiently recovered to enable the patient to cope with stressful emergencies, such as trauma, surgery or serious infections therefore patients should carry a steroid warning card. It may be advisable to provide a supply of corticosteroid tablets for use in these circumstances. Adrenocortical function should be monitored regularly. Patients may feel unwell during systemic steroid withdrawal but should be advised to persevere with their inhaled product and to continue with withdrawal of systemic steroids unless there is evidence of HPA axis suppression. Discontinuation of systemic steroids may cause exacerbation of allergic diseases. Therapy should be down-titrated to the lowest dose at which effective asthma control is maintained to minimise systemic effects. Prescribers should also be aware of risk of clinically significant adrenal suppression and acute adrenal crisis which may occur in patients on prolonged treatment with high doses of inhaled corticosteroids. Trauma, surgery, infection or any rapid reduction in dose could potentially trigger acute adrenal crisis. Use with caution in patients with active or latent pulmonary tuberculosis. Paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing. Paradoxical bronchospasm responds to a fast-acting bronchodilator and should treated straightaway. Kelhale discontinued immediately, with alternative therapy instituted, if necessary, following assessment. Visual disturbances may be reported with steroid use. Patients presenting with blurred vision or other visual disturbances should be considered for referral to an ophthalmologist. Patients should be advised that the inhaler contains a small amount of ethanol, which at normal doses are negligible and pose no risk to patients. Beclometasone is less dependent on CYP3A metabolism than some other corticosteroids and in general interactions are unlikely, however the possibility of systemic effects with strong CYP3A inhibitors cannot be excluded, therefore caution and appropriate monitoring is advised with use of such agents. **See the SmPC for further information on contraindications, precautions and interactions. PREGNANCY AND LACTATION**: The potential risk of this product in humans is unknown. Balance risks against benefits. **UNDESIRABLE EFFECTS:** Adverse events which have been associated with beclometasone dipropionate include: *Common (≥1/100 to <1/10)*; candidiasis of the mouth and throat, hoarseness, pharyngitis and taste disturbances. *Uncommon (≥1/1,000 to <1/100)*; headache, vertigo, tremor, blurred vision, cough, increased asthma symptoms, nausea, urticaria, rash, pruritus, erythema and purpura. Serious hypersensitivity, paradoxical bronchospasm, and systemic effects of inhaled corticosteroids can also occur. **For full details of adverse events please consult the SmPC. MARKETING AUTHORISATION HOLDER & NUMBER:** Cipla (EU) Limited. PLGB 36390/0229; PLGB 36390/0230. **Legal category:** POM. **NHS Cost:** 50 µg 1 x 200 actuations MDI £5.20; 100 µg 1 x 200 actuations MDI £5.20. **Date of last revision:** September 2022. Further information can be obtained from Cipla (EU) Ltd., Dixcart House, Addlestone Road, Bourne Business Park, Addlestone KT15 2LE.

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to Cipla (EU) Ltd on 0800 0472144, drugsafety@cipla.com