

## References:

1. Mundipharma International Limited. flutiform k-haler. Summary of Product Characteristics. Available from: <https://www.medicines.org.uk/emc/product/9483/smpc>. Last accessed October 2018.
2. Bell D et al. J Aerosol Med Pulm Drug Deliv 2017; 30:425–34.
3. MIMS. Available from: <https://www.mims.co.uk/search/drugs?keywords=Beta 2 agonists, long-acting/corticosteroids>. Last accessed July 2018.

### **flutiform® k-haler® (fluticasone propionate/formoterol fumarate) 50 µg/5 µg and 125 µg/5 µg pressurised inhalation suspension**

#### **Prescribing Information United Kingdom**

**Please read the Summary of Product Characteristics before prescribing.**

**Presentation** Pressurised inhalation suspension, in a breath-actuated pressurised aerosol inhaler. **Indications** Regular treatment of asthma where the use of a combination product (inhaled corticosteroid [ICS] and long-acting  $\beta$ 2-agonist [LABA]) is appropriate: (i) for patients not adequately controlled with ICS and 'as required' inhaled short-acting  $\beta$ 2-agonist (SABA) (ii) for patients already adequately controlled on both an ICS and a LABA. For adults and adolescents aged 12 years and above. **Dosage and administration** For inhalation use. Patients should be shown how to use the inhaler correctly by a healthcare professional. Patients should be given the strength of *flutiform k-haler* containing the appropriate fluticasone propionate dose for their disease severity (note that *flutiform k-haler* 50 µg/5 µg per actuation is not appropriate in patients with severe asthma). The appropriate strength should be taken as two inhalations, twice daily (normally morning and evening) and used every day, even when asymptomatic. *flutiform k-haler* is not recommended in children under 12 years. Prescribers should be aware that in asthmatics, fluticasone propionate is as effective as some other inhaled steroids when administered at approximately half the total daily microgram dose. Patients should be assessed regularly and once asthma is controlled, treatment should be reviewed and stepped down to the lowest effective dose, or an ICS alone. ICSs alone are first line treatment for most patients. *flutiform k-haler* is not intended for initial treatment of mild asthma. For patients with severe asthma the ICS therapy should be established before prescribing a fixed-dose combination product. Patients on *flutiform k-haler* must not use an additional LABA. An inhaled SABA should be taken for immediate relief of asthma symptoms arising between doses. Patients should be advised to contact their prescriber when *flutiform k-haler* dose counter is getting near zero. **Contraindications** Hypersensitivity to the active substances or to any of the excipients. **Precautions and warnings** *flutiform k-haler* should not be used as the first asthma treatment, to treat acute asthma symptoms or for prophylaxis of exercise-induced asthma. It should not be initiated during an exacerbation, during significantly worsening or acutely deteriorating asthma, and should not be stopped abruptly. If a patient experiences serious asthma-related adverse events or exacerbations, they should continue treatment and seek medical advice. Patients should be reviewed as soon as possible if there is any indication of deteriorating asthma control. In case of sudden and progressive deterioration, seek urgent medical assessment. Caution in patients with: pulmonary tuberculosis; quiescent tuberculosis; fungal, viral or other infections of the airway; thyrotoxicosis; phaeochromocytoma; diabetes mellitus (consider additional blood sugar controls); uncorrected hypokalaemia; predisposition to low levels of serum potassium; impaired adrenal function (monitor HPA axis function regularly); hypertrophic obstructive cardiomyopathy; idiopathic subvalvular aortic stenosis; severe hypertension; aneurysm or other severe cardiovascular disorders; unstable or acute severe asthma and other conditions when the likelihood for hypokalaemia adverse effects is increased. There is risk of potentially serious hypokalaemia with high doses of  $\beta$ 2-agonists or concomitant treatment with  $\beta$ 2-agonists and drugs that can induce or potentiate a hypokalaemic effect. Monitoring of serum potassium levels is recommended during these circumstances. Formoterol may induce prolongation of the QTc interval. Caution must be observed when treating patients with existing prolongation of QTc interval. *flutiform k-haler* should be discontinued immediately if there is

evidence of paradoxical bronchospasm. Visual disturbance may be reported with corticosteroid use. Systemic effects with an ICS may occur, particularly at high doses for prolonged periods or when combined with potent CYP3A4 inhibitors, but are less likely than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density and cataract glaucoma. Children may also experience anxiety, sleep disorders and behavioural changes. Increased exposure can be expected in patients with severe hepatic impairment. Prolonged treatment with high doses of corticosteroids may result in adrenal suppression and acute adrenal crisis, particularly in children and adolescents or potentially as a result of trauma, surgery, infection or rapid dose reduction. *flutiform k-haler* contains a negligible amount of ethanol that does not pose risk to patients. Interactions Co-treatment with CYP3A inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, ketoconazole, telithromycin, cobicistat) should be avoided unless the benefit outweighs the increased risk of systemic side-effects. Caution is advised with concomitant use of non-potassium sparing diuretics (e.g. loop or thiazide), xanthine derivatives, glucocorticosteroids, L-Dopa, L-thyroxine, oxytocin, alcohol or other adrenergic drugs, including anaesthesia with halogenated hydrocarbons and digitalis glycosides,  $\beta$ -adrenergic drugs, known to prolong the QTc interval, such as tricyclic antidepressants or MAOIs (and for two weeks following their discontinuation), antipsychotics (including phenothiazines), quinidine, disopyramide, procainamide, antihistamines. **Furazolidone and procarbazine** *flutiform k-haler* should not normally be used with  $\beta$ -blockers including those that are used as eye drops to treat glaucoma. Under certain circumstances, e.g. as prophylaxis after myocardial infarction, cardioselective  $\beta$ -blockers could be considered with caution. **Pregnancy and lactation** *flutiform k-haler* is not recommended during pregnancy unless the benefits to the mother outweigh risks to the foetus. A risk to the breastfeeding infant cannot be excluded. **Side-effects** Uncommon (<1/100) but potentially serious side-effects: hyperglycaemia, agitation, depression, aggression, behavioural changes (predominantly in children), vision blurred, vertigo, palpitations, ventricular extrasystoles, angina pectoris, tachycardia, hypertension, dyspnoea, peripheral oedema. Please consult the SPC for a full list of side-effects and those reported for the individual molecules. **Legal category** POM **Package quantities and price** One inhaler (120 actuations) 50 µg/5 µg - £14.40 125 µg/5 µg - £28.00 **Marketing Authorisation numbers** PL 16950/0338-39 **Marketing Authorisation holder** Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW UK Tel: 01223 424444 For medical information enquiries, please contact [medicalinformationuk@napp.co.uk](mailto:medicalinformationuk@napp.co.uk). FLUTIFORM is a registered trademark of Jagotec AG, and is used under licence. K-HALER is a registered trade mark of Mundipharma AG. © 2018 Napp Pharmaceuticals Limited.

**Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Napp Pharmaceuticals Limited on 01223 424444.**

UK/FLUT-K-18011

Date of Preparation: May 2018



**flutiform® k-haler®**  
fluticasone propionate/formoterol

**Intelligently designed. Simple to use.<sup>1,2</sup>**

