

flutiform® (fluticasone propionate and formoterol fumarate) pressurised inhalation suspension. Prescribing Information, United Kingdom. Please read the Summary of Product Characteristics before prescribing. Presentation: Pressurised inhalation suspension, in a pressurised metered dose inhaler (pMDI), containing fluticasone propionate and formoterol fumarate dihydrate at strengths of 50 µg/5 µg, 125 µg/5 µg or 250 µg/10 µg per actuation. **Indications:** Regular treatment of asthma where the use of a combination product (inhaled corticosteroid and long-acting β₂-agonist) is appropriate: For patients not adequately controlled with inhaled corticosteroids and ‘as required’ inhaled short-acting β₂-agonist (SABA), or for patients already adequately controlled on both an inhaled corticosteroid and a long-acting β₂-agonist (LABA). **flutiform** 50 µg/5 µg and 125 µg/5 µg per actuation are indicated for use in adults and adolescents 12 years and above. **flutiform** 250 µg/10 µg per actuation is only indicated for use in adults. **Dosage and administration:** For inhalation use. The patient should be shown how to use the inhaler correctly by a physician or other healthcare professional. Patients should be given the strength of **flutiform** containing the appropriate fluticasone propionate dose for their disease severity (note that **flutiform** 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 in the morning and evening) and used every day, even when asymptomatic. **flutiform** should not be used 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. Total daily dose can be increased if asthma remains poorly controlled by administering a higher strength inhaler. Appropriate doses of the β₂-agonist and inhaled corticosteroid (ICS) in separate inhalers, or the ICS alone, should be prescribed if a patient requires doses outside the recommended dose regimens. 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. It is extremely important to regularly review patients as their treatment is stepped down. ICSs alone are first line treatment for most patients. **flutiform** 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** must not use an additional LABA. An inhaled SABA should be taken for immediate relief of asthma symptoms arising between doses. **The AeroChamber Plus®** spacer device is recommended in patients who find it difficult to use inhalers; re-titration should always follow the introduction of a spacer device. Patients should be advised to contact their prescriber when the **flutiform** dose counter is getting near zero. **Contra-indications:** Hypersensitivity to any of the active substances or excipients. **Precautions and warnings:** **flutiform** should not be used for the first treatment of asthma, 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. Patients should use their **flutiform** maintenance treatment as prescribed, even when asymptomatic. If a patient experiences serious asthma-related adverse events or exacerbations, they should continue treatment but also seek medical advice. Patients should be reviewed as soon as possible if there is any indication of deteriorating asthma control. In the case of sudden and progressive deterioration, which is potentially life-threatening, an urgent medical assessment should be carried out. Use with caution in patients with: pulmonary tuberculosis; quiescent tuberculosis; fungal, viral or other infections of the airway; thyrotoxicosis; pheochromocytoma; 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. There is risk of potentially serious hypokalaemia with high doses of β₂-agonists or concomitant treatment with β₂-agonists and drugs that can induce or potentiate a hypokalaemic effect. Particular caution is recommended in unstable or acute severe asthma and other conditions when the likelihood for hypokalaemia adverse effects is increased. 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** should be discontinued immediately if there is evidence of paradoxical

bronchospasm. 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. Use of a spacer device may also cause an increased systemic exposure. 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 adolescents and children or potentially as a result of trauma, surgery, infection or rapid dose reduction. Patients should be advised that **flutiform** contains a small amount of ethanol; however this negligible amount does not pose a risk to patients. **flutiform** is not recommended in children under 12 years of age. **Interactions:** Caution is advised in long-term co-administration with strong CYP3A4 inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, ketoconazole and telithromycin); co-administration should be avoided if possible. Ritonavir in particular should be avoided, unless the benefits outweigh the risks of systemic side-effects. Caution is advised with use of non-potassium sparing diuretics (e.g. loop or thiazide), xanthine derivatives, glucocorticosteroids, L-Dopa, L-thyroxine, oxytocin, alcohol or other adrenergic drugs. There is an increased risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons. Hypokalaemia may increase the risk of arrhythmias in patients being treated with digitalis glycosides. Concomitant use of β-adrenergic drugs can have a potentially additive effect. Caution should be taken when using formoterol fumarate with drugs known to prolong the QTc interval, such as tricyclic antidepressants or MAOIs (and for two weeks following their discontinuation), as well as antipsychotics (including phenothiazines), quinidine, disopyramide, procainamide and antihistamines. Concomitant use of an MAOI or a similar agent, such as furazolidone or procarbazine, may precipitate hypertensive reactions. β-blockers and formoterol fumarate may inhibit the effect of each other. β-blockers may produce severe bronchospasm in asthma patients, and they should not normally be treated with β-blockers including those that are used as eye drops to treat glaucoma. Under certain circumstances, e.g. as prophylaxis after myocardial infarction, cardioselective β blockers could be considered with caution. **Pregnancy and lactation:** **flutiform** is not recommended during pregnancy. It should only be considered if benefits to the mother outweigh risks to the foetus. It is not known whether fluticasone propionate or formoterol are excreted in breast milk; a risk to the breast feeding infant cannot be excluded. A decision should be made on whether to discontinue breastfeeding or discontinue/abstain from **flutiform**. **Side-effects:** Potentially serious side-effects: hyperglycaemia; depression; aggression; behavioural changes (predominantly in children); paradoxical bronchospasm; agitation; vertigo; palpitations; ventricular extrasystoles; angina pectoris; tachycardia; hypertension; dyspnoea; peripheral oedema; Cushings Syndrome; adrenal suppression; growth retardation; cataract and glaucoma; hypersensitivity reactions and QTc interval prolongation. Please consult the SPC for details of non-serious side-effects and those reported for the individual molecules. **Legal category:** POM. **Package quantities and price:** One inhaler containing 120 actuations. 50 µg/5 µg - £14.40. 125 µg/5 µg - £28.00. 250 µg/10 µg - £45.56. **Marketing Authorisation numbers:** PL 16950/0167. PL 16950/0168. PL16950/0169. **Marketing Authorisation holder:** Napp Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW UK. Tel: 01223 424444. Member of the Napp Pharmaceutical Group. For medical information enquiries, please contact medicalinformationuk@napp.co.uk. **Date of preparation:** July 2015. **Date effective:** August 2015. ®FLUTIFORM is a registered trademark of Jagotec AG, and is used under licence. ®The ‘lung’ device (logo) is a registered trademark of Mundipharma AG. ®AEROCHAMBER and AEROCHAMBER PLUS are registered trademarks of Trudell Medical International. © 2012 Napp Pharmaceuticals Limited. UK/FLUT-15085

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