**flutiform®** (fluticasone propionate/formoterol fumarate)

50 μg/5 μg, 125 μg/5 μg and 250 μg/10 μg pressurised inhalation suspension

**Prescribing Information United Kingdom**

Please read the Summary of Product Characteristics (SPC) before prescribing.

**Presentation** A pressurised metered dose inhaler (pMDI) containing fluticasone propionate and formoterol fumarate dihydrate. **Indications** Regular treatment of asthma where the use of a combination product (inhaled corticosteroid [ICS] and long-acting β₂-agonist [LABA]) is appropriate: (i) for patients not adequately controlled with ICS and ‘as required’ inhaled short-acting β₂-agonist (SABA); (ii) for patients already adequately controlled on both an ICS and a LABA. flutiform pMDI 50 μg/5 μg is indicated for use in adults, adolescents and children aged 5 years and above; 125 μg/5 μg is indicated for use in adults and adolescents aged 12 years and above; flutiform pMDI 250 μg/10 μg is indicated for use in adults only. **Dosage and administration** Patients should be shown how to use the inhaler correctly by a healthcare professional. Patients should be given the strength of flutiform pMDI containing the appropriate fluticasone propionate dose for their disease severity (50 μg/5 μg per actuation is not appropriate in patients with severe asthma). To be used every day, two inhalations twice daily, even when asymptomatic. flutiform pMDI is not recommended in children under 5 years of age. Note: 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, except in children under 12 years. 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 pMDI is not intended for initial treatment of mild asthma. For severe asthma, ICS therapy should be established before prescribing a fixed-dose combination product. Patients on flutiform pMDI must not use an additional LABA. An inhaled SABA should be taken for immediate relief of asthma symptoms arising between doses. The AeroChamber Plus® Flo-Vu® spacer devices are recommended in patients who find it difficult to use inhalers; re-titration should always follow the introduction of a spacer device. **Contraindications** Hypersensitivity to the active substances or to any of the excipients. **Precautions and warnings** flutiform pMDI should not be used as the first treatment for asthma, to treat acute asthma symptoms nor for prophylaxis of exercise-induced asthma. Not to 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. In case of sudden and progressive deterioration of asthma control, an urgent medical assessment should be carried out. Caution in patients with: pulmonary or 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; severe cardiovascular disorders; unstable or acute severe asthma and other conditions when the likelihood for hypokalaemia adverse effects is increased. Potentially serious hypokalaemia may result from high doses of β₂ agonists or concomitant treatment with β₂ 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 pMDI should be discontinued immediately if there is evidence of paradoxical bronchospasm. Visual disturbance may be reported with systemic and topical corticosteroid use, if such symptoms present, consider for referral to an ophthalmologist. 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 side 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 experience anxiety, sleep disorders and behavioural changes. The use of a spacer device may cause an increased systemic exposure. Increased exposure can be expected in patients with severe hepatic impairment. Prolonged treatment with high doses of ICSs 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; height in this population should be regularly monitored. flutiform pMDI contains a negligible amount of ethanol which does not pose risk to patients. **Interactions** Co-treatment with strong CYP3A inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefilnavir, 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, anaesthesia with halogenated hydrocarbons, digitalis glycosides, β adrenergic drugs, drugs known to prolong the QTc interval such as tricyclic antidepressants, MAOIs (and for two weeks following their discontinuation), antipsychotics (including phenothiazines), quinidine, disopyramide, procainamide, antihistamines, furazolidone and procarbazine. 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. **flutiform** pMDI should not normally be used 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** 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: hyperglycaemia, agitation, depression, aggression, behavioural changes (predominantly in children), paradoxical bronchospasm, vision blurred, vertigo, palpitations, ventricular extrasystoles, angina pectoris, tachycardia, hypertension, dyspnoea, peripheral oedema, Cushing's Syndrome, adrenal suppression, growth retardation, cataract and glaucoma; hypersensitivity reactions and QTc interval prolongation. 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 - £28.00 250 µg/10 µg - £45.56 **Marketing Authorisation numbers** PL 16950/0167-69 **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. **® FLUTIFORM** is a registered trademark of Jagotec AG, and is used under licence. © 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.**