

含 formoterol/fluticasone 成分藥品之中文仿單修訂 參採內容 (CCDS 08-Apr-2019, V4 摘錄)

➤ 「**4.4 Special warning and precautions for use**」：

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for 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.

➤ 「**4.5 Interaction with other medicinal products and other forms of interaction**」：

Fluticasone propionate, an individual component of Flutiform inhaler, is a substrate of CYP3A4. Co-treatment with CYP3A inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, ketoconazole, telithromycin, cobicistat) is expected to increase the risk of systemic side-effects. Cases of Cushing’s syndrome and adrenal suppression have been reported. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

➤ 「**4.8 Undesirable effects**」：

System Organ Class	Adverse Event	Frequency
Eye disorders	Vision blurred	Not known