Ryaltris Prescribing Information
Ryaltris (mometasone furoate and olopatadine hydrochloride) **Please refer to the Summary of Product Characteristics (SmPC) before prescribing.** One delivered dose contains mometasone furoate monohydrate equivalent to 25 microgram mometasone furoate and olopatadine hydrochloride equivalent to 600 micrograms olopatadine. **Indication:** treatment of moderate to severe nasal symptoms associated with allergic rhinitis in adults and adolescents 12 years of age and older. **Posology and method of administration:** The usual recommended dose is two actuations in each nostril twice daily (morning and evening). *Children below 12 years:* Ryaltris is not recommended. Elderly: No dose adjustment required. *Renal and hepatic impairment:* there are no data in patients with renal and hepatic impairment, however no dose adjustment is expected to be required. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Ryaltris should not be used in the presence of untreated localised infection involving the nasal mucosa, such as herpes simplex. Patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred. **Precautions:** *Local nasal effects:* nasal ulceration and nasal septal perforation have been reported in patients following intranasal antihistamines. Nasal septal perforation has been reported following intranasal corticosteroids. Patients using Ryaltris over several months or longer should be examined periodically for possible changes in the nasal mucosa. Ryaltris is not recommended in cases of nasal septum perforation. In clinical studies with mometasone furoate administered intranasally, the development of localised infections of the nose and pharynx with *Candida albicans* has occurred; may require treatment and discontinuation of Ryaltris. Patients using Ryaltris over several months or longer should be examined periodically for evidence of Candida infection or other signs of adverse effects on the nasal mucosa. *Visual disturbances* may be reported with systemic and topical corticosteroid use. Symptoms such as blurred vision or other visual disturbances should be considered for ophthalmologist referral for evaluation of possible causes including cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR). *Hypersensitivity Reactions* including instances of wheezing, may occur. Discontinue Ryaltris if such reactions occur. *Immunosuppression:* Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible patients and those using corticosteroids. In children or adults who have not had these diseases or been properly immunized, particular care should be taken to avoid exposure. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, untreated local or systemic fungal or bacterial infections, systemic viral or parasitic infections, or ocular herpes simplex because of the potential for worsening of these infections. *Systemic Effects of Corticosteroids:* potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). When intranasal steroids are used at higher than recommended dosages or in susceptible individuals at recommended dosages, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, the dosage of Ryaltris should be discontinued slowly, consistent with accepted procedures for discontinuing oral corticosteroid therapy. The concomitant use of intranasal corticosteroids with other inhaled corticosteroids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency, and some patients may experience symptoms of withdrawal. Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical corticosteroids should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical conditions requiring long term systemic corticosteroid treatment, too rapid a decrease in systemic corticosteroids may cause a severe exacerbation of their symptoms. *Somnolence:* in isolated cases, dizziness, lethargy, fatigue and somnolence may occur when using Ryaltris. In these cases, the ability to drive and use machines may be impaired. Alcohol and other CNS depressants may enhance this effect. *Antihistamine effects:* concomitant use of other antihistaminic drugs administered may increase the risk of antihistamine adverse effects. *Paediatric population:* It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. *Excipients:* Ryaltris contains 0.02 mg benzalkonium chloride in each actuation. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. **Adverse reactions:** *Common (≥1/100 to <1/10):* dysgeusia (unpleasant taste), epistaxis, nasal discomfort. *Uncommon (≥1/1,000 to <1/100):* dizziness, headaches, somnolence, nasal dryness, dry mouth, abdominal pain, nausea, fatigue. *Rare (≥1/10,000 to <1/1000):* bacterial vaginosis, anxiety, depression, insomnia, lethargy, migraine, blurred vision, dry eye, eye discomfort, ear pain, nasal inflammation, nasal mucosal disorder, oropharyngeal pain, sneezing, throat irritation, constipation, sore tongue, laceration. *Incidence not known (reported from use of corticosteroids):* pharyngitis, upper respiratory tract infection, hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, and dyspnoea, cataracts, glaucoma, increased intraocular pressure, nasal septum perforation. **Marketing Authorisation number:** PL 25258/0331 **Marketing Authorisation Holder and distributer:** Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2B Draycott Avenue Kenton, Middlesex, HA3 0BU. United Kingdom **Legal classification:** POM **Cost:** £13.32. 1 bottle with 29 g suspension (240 actuations) **Date of preparation:** June 2021 **Job number:** PP-UK-RYAL-0001

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk.
Adverse events should also be reported to Glenmark Pharmaceuticals Europe Ltd medical_information@glenmarkpharma.com or call 0800 458 0383

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GLENMARK Respiratory

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