

Mometasone furoate and olopatadine hydrochloride nasal spray (Ryaltris®) for treatment of moderate to severe nasal symptoms associated with allergic rhinitis

The Cheshire and Merseyside Area Prescribing Group recommends the prescribing of mometasone furoate 25 micrograms and olopatadine hydrochloride equivalent to 600 micrograms nasal spray (Ryaltris®) for treatment of moderate to severe nasal symptoms associated with allergic rhinitis

GREEN

Ryaltris® is recommended as a treatment option for patients in whom:

- symptom control has not been achieved despite an adequate trial of therapy with intranasal antihistamine alone AND the addition of an intranasal corticosteroid is considered appropriate
OR
- symptom control has not been achieved despite an adequate trial of therapy with intranasal corticosteroid alone AND the addition of an intranasal antihistamine is considered appropriate.

Its position in the treatment pathway is the same as that for Dymista®.

Prescribing information

Ryaltris®

Adults and adolescents 12 years of age and older - TWO actuations in each nostril twice daily (morning and evening).¹

Implementation notes

Shelf life after opening

Ryaltris® - 2 months.¹

Note that for Dymista® the shelf life after opening is 6 months.²

Administration details

The method of administration is outlined in the patient information leaflet provided with the product.³

Driving and skilled tasks

Patients and carers should be cautioned on the effects on driving and performance of skilled tasks—increased risk of dizziness, lethargy, fatigue, and somnolence.^{1,4}

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Effectiveness

Ryaltris®

In a randomised double-blind study (n=1176) patients were randomised to receive 665 micrograms olopatadine + 25 micrograms mometasone or 665 micrograms olopatadine or 25 micrograms mometasone or placebo for 14 days; two sprays per nostril twice a day. The primary end point was mean change from baseline in average morning and evening 12 hour reflective Total Nasal Symptom Score (rTNSS). Twice daily 665 micrograms olopatadine + 25 micrograms mometasone had a statistically significant impact on the primary end point compared to placebo (p<0.001), olopatadine (p=0.03) and mometasone (p=0.02).⁵

In a randomised double-blind study (n=1180) patients were randomised to receive 665 micrograms olopatadine + 25 micrograms mometasone or 665 micrograms olopatadine or 25 micrograms mometasone or placebo for 14 days; two sprays per nostril twice a day. The primary end point was mean change from baseline in average morning and evening 12 hour reflective Total Nasal Symptom Score (rTNSS). Twice daily 665 micrograms olopatadine + 25 micrograms mometasone had a statistically significant impact on the primary end point compared to placebo (p<0.001), olopatadine (p=0.003) and non-significant impact compared to mometasone (p=0.059).⁶

Safety⁴

See [summary of product characteristics](#) and BNF for complete safety information including cautions.

All intranasal corticosteroids

Avoid after nasal surgery (until healing has occurred); avoid in pulmonary tuberculosis; avoid in the presence of untreated nasal infections; patients transferred from systemic corticosteroids may experience exacerbation of some symptoms. Systemic absorption may follow nasal administration particularly if high doses are used or if treatment is prolonged; therefore also consider the cautions and side-effects of systemic corticosteroids.

Common or very common side-effects: Altered smell sensation, epistaxis, headache, nasal complaints, taste altered, throat irritation.

Ryaltris®(excluding corticosteroid side effects already mentioned)

Uncommon side effects: Abdominal pain, dizziness, drowsiness, dry mouth, fatigue, headaches, nausea.

Cost⁷

Ryaltris® costs £13.32 (ex VAT) per 240 actuation pack. The annual cost per patient per year is £173.64

Dymista® (costs included for comparison) - £14.80 (ex VAT) per 120 actuation pack. The annual cost per patient per year is £192.93.

These costs assume that patients use it continuously whereas it may be used only when required for e.g. seasonal allergic rhinitis. See also implementation notes for information about product expiry dates.

Patient factors¹

Ryaltris®

Renal and hepatic impairment

There are no data in patients with renal and hepatic impairment, however no dose adjustment is expected to be required in these populations considering the absorption, metabolism and elimination of the active substances.

Interactions

Co-treatment with CYP3A inhibitors is expected to increase the risk of systemic side-effects. 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.

Pregnancy and Lactation

There are no or limited amount of data from the use of mometasone furoate in pregnant women. Studies in animals have shown reproductive toxicity. There are no or limited amount of data from the use of intranasal olopatadine in pregnant women. Studies in animals have shown reproductive toxicity following systemic administration. Ryaltris should not be used in pregnancy unless the potential benefit to the mother justifies any potential risk to the mother, foetus or infant. It is unknown whether mometasone furoate is excreted in human milk. Data in animals have shown excretion of olopatadine in milk following oral administration. A risk to the newborn/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Ryaltris therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

References

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3. Glenmark Pharmaceuticals (2023) Patient information Leaflet Ryaltris® available at: <https://www.medicines.org.uk/emc/files/pil.12898.pdf> Accessed 08.05.2024
4. British National Formulary (BNF) online. Available at: [BNF \(British National Formulary\) | NICE](#) Accessed 08.05.2024
5. Gross et al. (2019) Efficacy and safety of olopatadine-mometasone combination nasal spray for the treatment of seasonal allergic rhinitis. *Ann Allergy Asthma Immunol* 122; 630-638
6. Hampel et al. (2019) Olopatadine-mometasone combination nasal spray: Evaluation of efficacy and safety in patients with seasonal allergic rhinitis. *Allergy Asthma Proc* 40; 261-272
7. NHSBSA dm+d Browser. Available at: [dm+d browser \(nhsbsa.nhs.uk\)](#) Accessed 08.05.2024