

# Drug Profile: Ryaltris Nasal Spray

Rajaveni Panneerselvam<sup>1</sup>, Poongodi Venkatesan<sup>2</sup>

## ABSTRACT

Ryaltris is a metered, fixed-dose, prescribing nasal spray that delivers 665 µg of olopatadine hydrochloride, an antihistamine, and 25 µg of mometasone furoate monohydrate, a corticosteroid, in each spray. Ryaltris (olopatadine hydrochloride, mometasone furoate monohydrate) nasal spray has been approved by the Food and Drug Administration (FDA) for patients with 12 years and above for the treatment of symptoms associated with seasonal allergic rhinitis.

**Keywords:** Nasal spray, Ryaltris, Seasonal allergic rhinitis.

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## INTRODUCTION

Ryaltris is a prescribing nasal spray that contains two drugs, olopatadine hydrochloride and mometasone furoate monohydrate, and is used to treat the symptoms of seasonal allergic rhinitis (SAR) in patient aged 12 years and above. Ryaltris was approved by the FDA on January 13, 2022, to treat allergic rhinitis.<sup>1</sup> Olopatadine hydrochloride is an antihistamine that lessens the effects of histamine, a naturally occurring chemical in the body. Mometasone furoate monohydrate is a member of the corticosteroid class of drugs, which are used to treat inflammation. Due to rapid absorption, the drug is administered in the form of nasal spray.<sup>2</sup>

## INGREDIENTS

**Active ingredients:** Olopatadine hydrochloride and mometasone furoate monohydrate.

**Inactive ingredients:** Dibasic sodium phosphate heptahydrate, sodium chloride, microcrystalline cellulose, benzalkonium chloride, edetate disodium, carboxymethyl cellulose sodium, sodium hydroxide, hydrochloric acid, polysorbate 80, and water for injection.<sup>3</sup>

## DOSAGE

Two sprays in each nostril twice daily (1330 µg of olopatadine hydrochloride and 50 µg of mometasone furoate monohydrate) is the recommended dosage of Ryaltris nasal spray.<sup>4</sup>

## STORAGE

The drug should be stored at temperatures ranging from 20 to 25°C (68–77°F), with excursions allowed between 15 and 30°C (59–86°F). Store in a cool, dry place rather than a freezer or refrigerator.<sup>4</sup>

## INDICATION

- Seasonal allergic rhinitis
- Rhinoconjunctivitis

## CONTRAINDICATION

- Hypersensitivity
- Untreated localized infection involving nasal mucosa such as herpes simplex
- Recent nasal surgery and trauma

<sup>1,2</sup>Department of OBG Nursing, Kasturba Gandhi Nursing College, Puducherry, India

**Corresponding Author:** Rajaveni Panneerselvam, Department of OBG Nursing, Kasturba Gandhi Nursing College, Puducherry, India, Phone: +91 8056842628, e-mail: rajavenipanneerselvam94800@gmail.com

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## MECHANISM OF ACTION

The mechanisms of action for olopatadine hydrochloride and mometasone furoate monohydrate are as follows:

### Olopatadine Hydrochloride

Olopatadine works by inhibiting the histamine-1 (H1) receptor. In isolated tissues, animal models, and humans, olopatadine has been shown to have antihistaminic activity.

### Mometasone Furoate Monohydrate

Mometasone furoate monohydrate is an anti-inflammatory corticosteroid. The precise mechanism of action on allergic rhinitis is unclear. Corticosteroids have been shown to restrict a wide range of cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) as well as mediators of inflammation (e.g., histamine, leukotrienes, and cytokines).<sup>4</sup>

## PHARMACODYNAMICS

Ryaltris contains the active ingredients olopatadine hydrochloride and mometasone furoate monohydrate, which have different modes of action but work together to lessen allergic rhinitis symptoms. Olopatadine is a potent antiallergic/antihistaminic agent with a variety of distinct mechanisms of action. It minimizes histamine production (the primary mediator of allergic response in humans). Mometasone furoate monohydrate is a glucocorticosteroid with anti-inflammatory effects that are used topically. The ability to block the release of allergic reaction mediators is most likely the mechanism of antiallergic and anti-inflammatory actions. Leukotrienes from people with allergic leucocytes are greatly



Fig. 1: Ryaltris nasal spray

inhibited by it. Mometasone furoate monohydrate inhibited the synthesis and release of IL-1, IL-5, IL-6, and TNF in cell culture; it is also a strong inhibitor of production of leukotrienes. Furthermore, it inhibits the production of Th2 cytokines, IL-4 and IL-5, by human CD4+ T cells.<sup>5</sup>

## PHARMACOKINETICS

The mean ( $\pm$ standard deviation) peak plasma exposure ( $C_{max}$ ) for olopatadine hydrochloride was  $19.80 \pm 7.01$  ng/mL and  $9.92 \pm 3.74$  pg/mL for mometasone furoate monohydrate, and the mean exposure over the dosing regimen (AUC<sub>tau</sub>) for olopatadine hydrochloride was  $88.77 \pm 23.87$  ng\*hour/mL and  $58.40 \pm 27.00$  pg\*hour/mL for mometasone furoate monohydrate, after repeated intranasal administration of two sprays per nostril twice daily in patients with seasonal allergic rhinitis. For both olopatadine hydrochloride and mometasone furoate monohydrate, after a single dose, the median time to peak exposure was 1 hour. Mometasone furoate monohydrate and olopatadine hydrochloride did not show any pharmacokinetic interactions (Fig. 1).<sup>5</sup>

## SIDE EFFECTS

### Common Side Effects

- Nose bleeds
- Nasal discomfort
- Unpleasant taste
- Sleepiness or drowsiness
- Hypotension
- Weakness
- Nausea and vomiting
- Fever and body aches
- Breathing problems
- Swelling of face, mouth, and tongue

### Adverse Effects

- Impaired mental alertness and somnolence
- Cataracts and glaucoma
- Risk of infections and immunosuppression
- Adrenal suppression and hypercorticism
- Effect on growth

## DRUG INTERACTION

Ryaltris has not been subjected to any interaction studies. Because no pharmacokinetic interaction between olopatadine hydrochloride and mometasone furoate monohydrate was found when delivered together, any drug interactions from the combination probably match those of the components taken separately.<sup>4</sup>

## INSTRUCTIONS FOR USE

Shake the bottle fully before using the nasal spray.

**STEP 1:** Remove the cap of the nasal spray.

**STEP 2:** Hold the bottle securely and upright with the index and middle fingers on the finger rests on either side of the applicator and the thumb on the bottle's grooved base.

**STEP 3:** Before using the nasal spray, squeeze the pump six times rapidly and strongly to expel the spray into the air, away from the face and eyes, until a fine sprays emerges.

**STEP 4:** Blow the nose gently to clear the nostrils.

**STEP 5:** Before each use (morning and evening), shake the nasal spray bottle properly.

**STEP 6:** With the index and middle fingers on either side of the applicator, hold the bottle firmly, while the thumb rests on the bottle's grooved base.

**STEP 7:** With your finger, close one nostril. Place the spray pump tip in the opposite nostril, slightly away from the nasal septum towards the outside of nose (the wall between the two nostrils).

**STEP 8:** Slightly tilt the head forward. To activate the pump, hold the bottle upright and push down quickly and firmly on the finger rests. As you spray, gently inhale (breathe in) through the nose. Exhale through the mouth.

**STEP 9:** Repeat steps 6–8, second spray should be delivered into the same nostril as same as first.

**STEP 10:** Steps 6–8 should be repeated, but this time with two sprays in the opposite nostrils. To ensure that you receive all the medication, do not blow your nose for at least 15 minutes after using Ryaltris. Do not move the head back. This will retain the drug from entering the throat.

**STEP 11:** With a dry tissue or cloth, clean the bottle and spray pump tip.

**STEP 12:** Push the dust cap back on the spray pump tip, until you hear a click sound.

**STEP 13:** Pull the spray pump unit upward gently if it becomes obstructed. Remove the dust cap from the spray pump unit and soak it in warm water.

**STEP 14:** After 15 minutes of rinsing, clean the spray pump unit and dust cap with warm water and allow them to dry completely.

**STEP 15:** Replace the spray pump unit on the bottle and the dust cap on the spray pump tip.

**STEP 16:** After completing the steps to clear the obstructed spray pump. Replace the dust cap, and the Ryaltris nasal spray is ready to use.<sup>4</sup>

## NURSES RESPONSIBILITIES

- Instruct the patient to gently blow the nose to clear the nostrils before administering the first dose.

- After the first priming, instruct the patient to throw away the bottle after using 240 sprays. Even if the bottle is not totally empty, continuing to use it may result in the wrong dose of medicine being administered.
- Instruct the patient if they are self-administering the drug; inform them to follow the instructions in the leaflet.
- Instruct the patients not to engage in the hazardous activities such as driving and operating machinery which may cause sleepiness or drowsiness.
- Inform the patient not to drink alcohol or take any other drugs that may make them sleepy while taking Ryaltris.

## CONCLUSION

Ryaltris nasal spray is a white liquid suspension in a plastic bottle with a manual spray pump with a white actuator and a purple cap for intranasal administration. It contains olopatadine hydrochloride and mometasone furoate monohydrate, both of which act in different ways and have synergistic effects. It

is approved for the treatment of moderate-to-severe nasal symptoms associated with allergic rhinitis in adults and adolescents 12 years of age and older.

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