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Review Article

Chlorpheniramine and Phenylephrine in the Management of Common Cold and Allergic Rhinitis in Pediatric Patients

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Abstract

The common cold, a prevalent viral respiratory illness, affects the upper respiratory tract and is frequently caused by rhinoviruses. Characterized by symptoms such as rhinorrhea, nasal congestion, and cough, the common cold is particularly burdensome for young children who experience multiple episodes annually. Allergic rhinitis, although less common, also presents with similar symptoms triggered by IgE-mediated hypersensitivity to allergens. Management of these conditions typically involves symptomatic relief using antihistamines, decongestants, and analgesics. Chlorpheniramine maleate (CPM), a first-generation antihistamine, and phenylephrine, a nasal decongestant, are commonly used to address symptoms of both conditions. Recent restrictions in India limit the use of fixed-dose combinations of CPM 2 mg and phenylephrine 5 mg/mL oral drops in children under 4 years. However, oral drops containing CPM 1 mg and phenylephrine 2.5 mg/mL have been found effective and well-tolerated in infants and young children. Studies have shown significant reductions in symptom severity with minimal adverse effects, supporting their use in treating pediatric colds and allergic rhinitis. This review discusses the efficacy, tolerability, and recommended dosing of these oral drops, emphasizing their role in symptom management while highlighting the importance of cautious use and monitoring for potential side effects.

Key words: Allergic rhinitis, Allergies, Chlorpheniramine maleate, Common cold, Pediatric patients, Phenylephrine

INTRODUCTION

Common cold represents one of the most prevalent viral respiratory illnesses and the most common cause of visiting physicians.[1-3] It mainly affects the upper respiratory tract, and it may sometimes affect the lower respiratory tract.[1,2] Various respiratory viruses, with rhinovirus being the most frequent, are responsible for causing the common cold.[1,2]

The common cold is characterized by symptoms, such as rhinorrhea, nasal congestion, sneezing, sore or scratchy throat, headaches, myalgia, and fever.[1,4,5] It has been observed that 40% of individuals in India exhibit cold or cough symptoms at least once every 6 months.[5] However, the occurrence of common cold episodes declines with increasing age.[6]

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Children are particularly vulnerable due to their lack of developed immunity to numerous viruses, suboptimal personal hygiene practices, and frequent interaction with other children who may harbor viral infections.[4,6] On an average, young children experience 7–10 episodes of colds annually.[4,7] Typically, the common cold is self-limiting and symptoms generally improve within 1–2 weeks.[1,2,8] Infants and preschool children with colds are likelier to develop fever. Nasal congestion can hamper sleep and result in fatigue and irritability.[2] Furthermore, no antivirals are available for its treatment[7] and treatment primarily focuses on alleviating symptoms and preventing them from worsening.[6-8]

Allergic rhinitis is a nasal condition characterized by symptoms triggered by IgE-mediated hypersensitivity

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reactions to allergens. Its cardinal symptoms include watery rhinorrhea, nasal congestion, nasal itching, and sneezing.[7,9] Although less frequent than the common cold, allergic rhinitis is also fairly common and affects nearly 40% of children in some parts of their lives.[7,10] The signs and symptoms of allergic rhinitis are similar to those of the common cold, and both conditions present in a comparable manner.[11]

Treatments aimed at alleviating symptoms include antihistamines, decongestants, and analgesics or antipyretics, which are administered either individually or in combination.[11,12] The commonly found oral decongestants in over-the-counter products include phenylephrine and pseudoephedrine.[12] Similarly, commonly used antihistamines include brompheniramine, chlorpheniramine, clemastine, diphenhydramine, cetirizine, fexofenadine, and others.[10-12] Since a single drug may not effectively alleviate all symptoms, combinations of multiple medications are often used to address the various symptoms in these conditions.[7,11]

Phenylephrine, a nasal decongestant, and chlorpheniramine maleate (CPM), an antihistamine, are commonly combined for alleviating symptoms in both the common cold and allergic rhinitis.[7,13,14] However, recently fixed drug combinations (FDCs) containing CPM 2 mg and phenylephrine 5 mg/mL oral drops have been restricted for use in children below 4 years in India.[15,16] On the contrary, oral drops containing CPM 1 mg and phenylephrine 2. 5 mg/mL have been demonstrated to be effective and well-tolerated in infants.[14] In addition, oral drops containing CPM 1 mg, phenylephrine 2. 5 mg, and paracetamol 125 mg have been reported to be effective and well-tolerated in infants and young children.[4,7]

Thus, the present review discusses the role of this combination and the use of oral drops containing CPM 1 mg and phenylephrine 2.5 mg/mL in the management of common cold and allergic rhinitis in the pediatric population based on the opinion of 21 experts across India.

PHARMACODYNAMICS OF CPM AND PHENYLEPHRINE

Antihistamines are commonly used to alleviate symptoms such as a runny nose, sneezing, and itchy and watery eyes associated with the common cold.[12] Chlorpheniramine, a first-generation antihistamine, competitively binds to H1 receptors in the vascular tunica media of the nasal mucosa, inhibiting histamine-induced vasoactive responses.[4,6,7] This blocks histamine action at nasal H1 receptors, thereby preventing allergic responses and providing anti-allergic and anti-inflammatory effects in the nasal mucosa.[4,6] This mechanism effectively alleviates symptoms like sneezing, nasal congestion, and discharge, making it a preferred treatment for histamine-mediated allergies.[4,6] The anti-allergic and anti-inflammatory properties are complemented by its anticholinergic effects which help reduce infectious nasal discharges.[7]

First-generation antihistamines are considered better than second-generation options for treating these symptoms. Unlike second-generation antihistamines, which do not cross the blood-brain barrier, the effectiveness of first-generation agents such as chlorpheniramine stems from their interaction with histaminic and muscarinic receptors in the medulla.[12]

Nasal decongestants appear to offer modest effectiveness in providing short-term relief from cold symptoms.[17] Phenylephrine acts as a selective alpha-1 adrenergic receptor agonist.[4,6] Activation of these receptors either by direct binding of the sympathomimetic agent to the binding site of the receptor or by increasing norepinephrine release induces vasoconstriction. This action mitigates nasal blockage resulting from inflammation. The resultant vasoconstriction reduces tissue volume by decreasing blood flow within the nasal mucosa.[7] Thus, phenylephrine effectively reduces nasal congestion by constricting blood vessels in the nasal passages and decreasing nasal mucus production.[4,6]

RATIONALE FOR COMBINATION THERAPY

Although first-generation antihistamines provide short-term relief from symptoms such as rhinorrhea, nasal congestion, and sneezing when used alone, they are more effective, when combined with decongestants and antipyretics.[12] Although antipyretics can be part of a fixed-dose combination along with antihistamine and decongestant, many treating physicians prefer it without antipyretic, especially when the patient is afebrile. Even in patients with fever, they prefer to give antipyretic separately.[14]

SAFETY OF CPM AND PHENYLEPHRINE

While each component has demonstrated individual safety profiles, careful consideration is needed for the combination, particularly in pediatric patients who may show more pronounced variations in drug response and susceptibility to adverse effects.[4]

Antihistamines are commonly prescribed for children, despite ongoing concerns about their adverse effects,

particularly in early childhood.[18] First-generation antihistamines, in particular, are known for their sedative effects.[12,18] They also exhibit antimuscarinic, antiadrenergic, and antiserotonergic activities, which can manifest as vision disturbances, dry mouth, rapid heart rate, and confusion.[18]

Before initiating antihistamine treatment, it is essential to counsel the family regarding proper use. This includes information on dosing frequency, expected clinical effects, and potential side effects, particularly with first-generation antihistamines.[19]

Decongestants are generally safe when used correctly, but they can cause numerous adverse effects due to their direct interaction with adrenergic receptors and stimulation of the central nervous system (CNS).[12]

STUDIES ON EFFICACY AND TOLERABILITY OF ORAL DROPS CONTAINING CPM 1 MG AND PHENYLEPHRINE 2.5 MG/ML

Kiran and Pawaskar conducted a Phase IV clinical trial across 12 pediatric centers in India to evaluate the efficacy and tolerability of this combination in allergic rhinitis [Table 1]. This study indicated that a combination of phenylephrine 2.5 mg and CPM 1 mg offers optimal symptomatic relief and is safe for treating allergic rhinitis in infants. These medications must be administered at appropriate doses tailored to the severity and duration of the symptoms.[14]

STUDIES ON EFFICACY AND TOLERABILITY OF ORAL DROPS CONTAINING CPM 1 MG, PHENYLEPHRINE 2.5 MG, AND PARACETAMOL 125 MG

The evidence on CPM 1 mg and phenylephrine 2.5 mg/mL in the treatment of the common cold is limited. However, two studies have demonstrated the tolerability and efficacy of oral drops containing CPM 1 mg, phenylephrine 2.5 mg, and paracetamol 125 mg/mL for treating common cold symptoms in children.[4,7]

Kiran *et al.* conducted an open-label, multi-center study involving 200 pediatric patients under 1 year of age who presented with symptoms of the common cold or allergic rhinitis. The study evaluated the efficacy and tolerability of oral drops containing 1 mg CPM, 2.5 mg phenylephrine, and 125 mg paracetamol. The results demonstrated that these drops were both effective and well-tolerated for managing symptoms of the common cold and allergic rhinitis in this age group [Table 1].[7]

In another study, Dewan *et al.* evaluated the tolerability and efficacy of this combination in 200 children aged 2–5 years with symptoms of the common cold. The findings indicated that the oral drops were both well-tolerated and effective in alleviating common cold symptoms in this young pediatric population [Table 1].[4]

PLACE IN THERAPY

Phenylephrine acts as a decongestant, reducing nasal congestion, while chlorpheniramine serves as an antihistamine, addressing symptoms such as sneezing, runny nose, and itching.[4,6,17,18]

The fixed-dose combination of 1 mg CPM and 2.5 mg phenylephrine per mL in oral drops has proven well-tolerated and effective for treating allergic rhinitis in infants.[14] In addition, when combined with paracetamol, this formulation has shown efficacy in managing common cold symptoms in children aged 2–5 years and allergic rhinitis/cold in infants.[4,7]

In addition, oral drops containing this strength of chlorpheniramine and phenylephrine along with paracetamol have been approved by Central Drugs Standard Control Organization in India since 2021.[20] The use of a combination of nasal decongestants, antihistamines, and non-steroidal anti-inflammatory drugs (NSAIDs) is established for treating the common cold, supported by substantial clinical evidence, including the studies previously discussed. However, allergic rhinitis occurs generally without fever and involves minimal pain, so NSAIDs are usually not required.[14]

The tolerability of CPM and phenylephrine combination, especially in infants, has also been established in some recent studies.[7,14] The common side effects reported in these studies include sedation and drowsiness.[7,14]

Thus, this strength of the components in combination offers a well-tolerated and effective treatment option for both common cold symptoms and allergic rhinitis in young patients.

DOSE AND ADMINISTRATION

For children aged 2–6 years, the typical dose of CPM is 1 mg every 4–6 h, not to exceed 6 mg in 24 h.[21] In comparison, the recommended dose for diphenhydramine

Table 1: Studies on efficacy and tolerability of oral drops in treating common cold and allergic rhinitis

Authors	Kiran and Pawaskar[14]	Kiran *et al*.[7]	Dewan *et al*.[4]
Study details	Open-label, multi-centric study	Open-label, multi-centric, post-marketing surveillance study	Open-label, prospective, multi-centric, active post-marketing surveillance study
Duration	5 days	5 days	5 days
Participants	215 infants	200 infants	200 children
Inclusion criteria	• Age: 1–12 months • Body weight: 2–12 kg • Patients whose guardians were ready to adhere to the protocol	• Aged <1 year • Common cold or allergic rhinitis • Body weight: 2.5–11.8 kg	• Age: 2–5 years • Common cold symptoms
Exclusion criteria	• Known hypersensitivity to the study drugs • Patient's guardians unwilling to sign Informed Consent form	• Known hypersensitivity to the study drugs • Guardian of the patient who could not adhere to the protocol	• Hypersensitivity to formulation ingredients • Hepatocellular insufficiency • Active liver disease or hepatic failure • Use of antihistamines, analgesics, or decongestants within 1 day before enrolment • Those deemed inappropriate for inclusion by the investigator
Medication	Oral drops: Chlorpheniramine maleate 1 mg and phenylephrine 2.5 mg/mL	Oral drops: Chlorpheniramine maleate 1 mg, phenylephrine 2.5 mg, and paracetamol 125 mg	Oral drops: Phenylephrine 2.5 mg, chlorpheniramine maleate 1 mg, and paracetamol 125 mg/mL
Dosage	• 0.2 mL twice daily for infants 1–6 months old and weighing 2–9.7 kg • 0.4 mL twice daily for infants 7–12 months old and weighing 6.7–12 kg	• 0.2 mL three or four times a day in infants 1–6 months old and weighing 2.5–9.7 kg • 0.2–0.4 mL 3 or 4 times a day in infants 7–12 months old and weighing 6.7–11.8 kg	1 mL every 4–6 h for 5 days
Other allowed treatments	Steam inhalation and warm water	Non-pharmacological measures	Steam inhalation and warm water at regular intervals
Baseline mean TSS	5.677	5.91	0.95
Mean TSS on day 3	2.711 (52.23% reduction from baseline)	3.57 (39.48% reduction from baseline)	N/A
Mean TSS on day 5	0.542 (90.44% reduction from baseline)	1.47 (75.05% reduction from baseline)	0.02
Statistical Significance	Significant reduction in TSS (P<0.001)	Considerable reductions in TSS observed over 5 days	Significant reductions in symptom severity scores from day 1 to day 5 (P<0.001)
Adverse events	39 events among 15.25% of patients, with 14.1% experiencing sedation and drowsiness	8 episodes of ADRs, including sedation and drowsiness	None reported
Serious adverse events	None reported	None reported	None reported
Improvements in general and physical examinations	Observable improvements	N/A	N/A
Patients completing the study	177 out of 215	164 out of 200	All
Complete remission	Majority of patients	N/A	82% (164 out of 200)
Parent and investigator ratings	N/A	N/A	92.5% of parents and 97.5% of investigators rated the oral drops as good to excellent for managing symptoms

TSS: Total symptom score

in children aged 2–6 years is 5 mg/kg/day every 6 h as needed and daily dose not exceeding 300 mg. Furthermore, diphenhydramine should not be used in neonates owing to possible CNS effects. Lastly, brompheniramine dose in patients aged 2–6 years is 1 mg every 4–6 h.[22]

In the case of phenylephrine, the dose is 2.5 mg every 4 h or 3.75 mg every 6 h, with a maximum daily dose of 15 mg for children aged 2–6 years.[22,23] In comparison, pseudoephedrine dose in children aged under 12 years is 4 mg/kg/day every 6 h as needed, with a maximum daily dose of 60 mg.[22] Furthermore, studies on the efficacy and safety of pseudoephedrine preparations in children have not produced conclusive results. Most reports advise caution in using these medications for children under 12 years of age.[24]

Specifically, in the case of infants (1–2 years), the evidence available includes doses for oral drops based on their age [Table 2].[25]

Table 2: Doses for oral drops containing chlorpheniramine maleate 1 mg and phenylephrine 2.5 mg/mL

Age	Dose
1–6 months	0.2 mL thrice or 4 times a day
7–12 months	0.2–0.4 mL thrice or 4 times a day
1–2 years	0.4–0.8 mL thrice or 4 times a day

CONCLUSION

The fixed-dose combination of CPM and phenylephrine is an effective and well-tolerated treatment for common cold and allergic rhinitis in pediatric patients. Phenylephrine reduces nasal congestion, while chlorpheniramine alleviates symptoms such as sneezing and runny nose. Clinical studies support its efficacy in infants and children aged 2–5 years, showing significant symptom relief with minimal adverse effects. However, careful dosing is necessary due to potential side effects, including sedation and CNS stimulation.

EXPERT OPINION

Dr. Arun Dubey, M.B.B.S., D.C.H., Thane, Maharashtra

The combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg is an effective and safe option for managing symptoms of the common cold and other upper respiratory tract infections in children. This combination quickly relieves symptoms such as runny nose, sneezing, and nasal congestion with minimal side effects. In my practice, I recommend the combination of chlorpheniramine and phenylephrine for children who have symptoms of the common cold.

Dr. Bhadra B, M.B.B.S., M.D. (Pediatrics), Hyderabad, Telangana

The combination of CPM and phenylephrine demonstrates good efficacy in treating severe common cold symptoms with acceptable tolerability, making it a preferred choice for eligible patients. The added anticholinergic activity of CPM is particularly beneficial for effectively relieving rhinorrhea and allergic symptoms. In my experience, CPM 1 mg and phenylephrine 2.5 mg drops have been effective in alleviating rhinorrhea, nasal congestion, and sneezing. The low doses of these constituents can be safely administered to children.

Dr. Bindu Saravanan, M.B.B.S., M.D. (Pediatrics), Salem, Tamil Nadu

I have observed that combination of chlorpheniramine and phenylephrine is safe and effective when prescribed as per the recommended dosing regimen. The FDC is well tolerated by all the patients. The FDC has been found to be effective in relieving rhinorrheas, nasal congestion, and sneezing. Low doses of the constituents can be safely given to children.

Dr. Chinnasamy Prabhakarn, M.B.B.S., D.C.H, Kovilpatti, Tamil Nadu

Combining chlorpheniramine 1 mg and phenylephrine 2.5 mg is an effective and safe method for managing common cold symptoms and other upper respiratory tract infections in children. This combination rapidly alleviates symptoms such as runny nose, sneezing, and nasal congestion with minimal side effects. I routinely recommend this combination for children with allergic rhinitis symptoms in my practice.

Dr. Deepthi Rayi, M.B.B.S., D.C.H, DNB (Pediatrics), Hyderabad, Telangana

First-generation antihistamines like chlorpheniramine are highly efficacious against allergic symptoms. If the symptoms are severe, I recommend these molecules over newer-generation antihistaminics. These molecules can be given to patients where sedation is not a problem. In my clinical practice, CPM combination with decongestants like phenylephrine, helps to prevent and treat nasal and ocular itching, rhinorrhea, and sneezing associated with the common cold effectively.

Dr. E. Dhinesh, D.C.H., DND (Peads), P.G.P.N., Rasipuram, Tamil Nadu

I believe that children suffering from sneezing and rhinorrhea should have access to symptom relief with minimal side effects. The combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg drops is highly effective in providing this relief. The combination has been found to be quite effective with acceptable tolerability in most of my patients.

Dr. Gaurav Monga, M.B.B.S., M.D. (Pediatrics), Bathinda, Punjab

The combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg is an effective treatment for managing allergic rhinitis in children. This combination targets multiple symptoms of allergic rhinitis with minimal side effects. In clinical practice, it is recommended for children with a variety of symptoms, offering quick and efficient relief to improve allergic rhinitis symptoms.

Dr. Gourav Garg, M.B.B.S., M.D. (Pediatrics), Bathinda, Punjab

In my opinion, Chlorpheniramine 1 mg and phenylephrine 2.5 mg could be highly beneficial for children seeking symptomatic relief within 3–5 days. This combination is particularly effective for the pediatric population, offering relief with minimal side effects.

Dr. J. Saravanan, M.B.B.S., D.C.H, MRCPCH (UK), MRCP (Edn), Pondicherry

In my opinion, chlorpheniramine 1 mg and phenylephrine 2.5 mg demonstrate beneficial effects within 3–5 days for patients suffering from common cold symptoms. These medications help to reduce both nasal and non-nasal symptoms effectively in children.

Dr. Jaskaran Singh Sawhney, M.B.B.S., M.D. (Pediatrics), Chandigarh

The combination of CPM and phenylephrine is effective in managing severe common cold symptoms while maintaining an acceptable level of tolerability, making it a favorable option for a suitable pediatric population. The anticholinergic properties of CPM are especially helpful in reducing rhinorrhea and allergic symptoms. Based on my experience, CPM 1 mg and phenylephrine 2.5 mg drops have relieved rhinorrhea, nasal congestion, and sneezing.

Dr. M. Senthilkumar, M.B.B.S., M.D. (Gen), D.C.H., Salem, Tamil Nadu

In my opinion, children experiencing sneezing and rhinorrhea require symptom relief with minimal side effects. The combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg drops provides effective relief for these symptoms. Many children show improvement in their total symptom score within 3 days.

Dr. M.S.N. V.S.R.K. Ramesh, M.B.B.S, D.C.H., Bhimavaran, Andhra Pradesh

In my practice, I have found the combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg to be highly effective for managing common cold symptoms in children. This combination is particularly helpful for those experiencing multiple symptoms, especially at night when cold symptoms can interfere with sleep. Chlorpheniramine's mild sedative effect can aid in improving sleep quality, while both medications work together to alleviate runny nose, sneezing, and nasal congestion.

Dr. Mahendra Patel, M.B.B.S., M.D. (Pediatrics), Mumbai, Maharashtra

In my clinical experience, the combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg is highly effective for managing common cold symptoms in children. This formulation is particularly useful at night when symptoms can interfere with sleep. Additionally, the combination effectively addresses symptoms such as runny nose, sneezing, and nasal congestion, providing comprehensive relief and improving overall comfort during illness.

Dr. Pramod Jog, M.B.B.S., M.D. (Pediatrics), Pune, Maharashtra

In my opinion, the combination of phenylephrine 1 mg and chlorpheniramine 2.5 mg offers several benefits for managing common cold symptoms in children. This combination effectively targets multiple symptoms of the common cold, including nasal congestion, runny nose, and sneezing, providing comprehensive relief.

Dr. Prashant Vaidya, M.B.B.S., M.D. (Pediatrics), Mumbai, Maharashtra

Chlorpheniramine, an antihistamine, effectively reduces symptoms such as runny nose, sneezing, and itching by blocking histamine receptors. Phenylephrine, a decongestant, reduces nasal congestion by constricting blood vessels in the nasal passages. Together, these medications provide comprehensive relief from multiple symptoms associated with the common cold. I prefer this combination in most children but not all, but both chlorpheniramine and phenylephrine have a well-established safety profile when used at appropriate doses in children.

Dr. Praveen Mehta, M.D., D.C.H., Mumbai, Maharashtra

In my clinical experience, the combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg has proven to be highly effective in managing common cold symptoms in children. It is particularly beneficial for those presenting with multiple symptoms, especially at night when cold-related discomfort can disrupt sleep.

Dr. R. V. Madhvi, M.B.B.S., D.C.H, Hyderabad, Telangana

The combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg is a potent treatment for managing allergic rhinitis in children. This dual-action medication effectively addresses various symptoms of allergic rhinitis with minimal adverse effects. In clinical practice, it is advised for children presenting with multiple symptoms, offering swift and significant relief to enhance their condition.

Dr. Ramesh Pillarisetty, M.B.B.S., D.C.H, Kakinada, Andhra Pradesh

In my opinion, when used judiciously, the combination of chlorpheniramine and phenylephrine gives early relief to allergic rhinitis symptoms. The combination is particularly effective in rhinorrhea and sneezing. The combination has been found to be quite effective with acceptable tolerability in most of my patients.

Dr. Shripad Kumar, M.B.B.S., D.C.H, Hyderabad, Telangana

The combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg is a highly effective treatment for managing allergic rhinitis in children. This combination offers a balanced approach, targeting multiple symptoms of allergic rhinitis with minimal side effects. In clinical practice, it is recommended for children experiencing a range of symptoms, providing quick and effective relief to improve symptoms of AR.

Dr. Sunil Kumar, M.B.B.S., D.N.B. (Pediatric), Hyderabad, Telangana

In my practice, the combination of chlorpheniramine 1 mg and phenylephrine 2.5 mg drops has proven to be highly effective in managing symptoms of the common cold in children. This combination is particularly advantageous for those suffering from multiple symptoms, especially during night-time when cold symptoms can hinder sleep.

Dr. V. Uma Shankar, M.B.B.S., M.D. (Pediatrics), Bhimavaran, Andhra Pradesh

At therapeutic dosage phenylephrine causes vasoconstriction in the nasal mucosa, relieving the nasal blockage cause due to inflammation. CPM is one of the most often recommended and used 1st generation antihistaminic agent. In my opinion, this FDC provides relief from runny nose, sneezing, and nasal congestion with minimal side effects when used appropriately.

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