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Dear Healthcare Professionals,

Nasal decongestant sprays and drops containing xylometazoline hydrochloride / oxymetazoline hydrochloride: increased risk of rebound congestion, rhinitis medicamentosa, and tachyphylaxis with overuse

Your attention is drawn to the following Medicines and Healthcare products Regulatory Agency's (MHRA) announcement related to nasal decongestant sprays or drops containing xylometazoline hydrochloride and oxymetazoline hydrochloride, and the increased risk of rebound congestion, rhinitis medicamentosa, and tachyphylaxis with overuse.

Summary

There have been reports of worsening nasal congestion (rebound congestion) when the effects of nasal decongestant sprays or drops containing xylometazoline hydrochloride and oxymetazoline hydrochloride, referred to hereafter as 'xylometazoline' and 'oxymetazoline', wear off. This typically occurs when these medicines are used for longer than recommended. Continued use can also lead to more serious and longer-lasting changes to the lining and structures of the nose (rhinitis medicamentosa). In addition, repeated use will result in a rapid and noticeable reduction in the medicine's effectiveness (tachyphylaxis).

Patients and caregivers should be informed not to exceed the recommended dose and not to use for more than 5 consecutive days. Continuous use of these medicines for more than 5 days can lead to an increased risk of side effects. Medical advice should be sought if symptoms of nasal congestion persist, worsen or do not improve after 5 days, as alternative treatment may be required.

Advice for Healthcare Professionals:

- rebound congestion, rhinitis medicamentosa, and tachyphylaxis through overuse are recognised side effects with nasal sprays and drops containing xylometazoline or oxymetazoline when used beyond the maximum recommended duration
- patients may mistakenly interpret a rebound congestion effect as a continuation of the original

congestion when it is a response to prolonged use of the product

- advise patients and their caregivers that xylometazoline and oxymetazoline are for short term use only and advise against prolonged or extended use beyond 5 days
- advise patients and their caregivers not to exceed the daily recommended dose and to take note of the minimum dosing interval stated in the product information
- if the symptoms of nasal congestion persist, worsen or do not improve after 5 days, alternative treatment may be required
- patients experiencing rebound congestion or related side effects may feel the need to continue using the products, leading to a cycle of overuse. Opportunistically review patients who may have become reliant on using these products and advise them on how to gradually stop using these medications. Stopping abruptly can worsen symptoms, but patients typically recover within 3 months with early recognition and treatment
- rhinitis medicamentosa is the most serious of these reported effects and is associated with persistent nasal congestion and longer-lasting changes to the nasal mucosa or structures of the nose. Symptoms may not resolve quickly after stopping the decongestant and, in severe cases, may require surgical intervention. Look out for patients presenting with severe nasal congestion and visible changes to the nasal mucosa or other internal nasal structures. Associated symptoms may include nasal irritation or itching, sneezing, and a runny nose. Management may require a tailored treatment plan, including gradual withdrawal of the decongestant, use of alternative therapies, and clinical follow-up to monitor recovery
- use of the nasal sprays or drops containing xylometazoline or oxymetazoline is contraindicated in patients who are taking other oral and nasal forms of sympathomimetic decongestants
- the product information will be transitioning over the next few months towards strengthened warnings regarding these side effects and to advise that they should not be used for more than 5 days

Advice for Healthcare Professionals to Provide to Patients:

- nasal sprays and drops containing xylometazoline and oxymetazoline are used to help clear a blocked nose, caused by cold, flu and allergies
- you can buy these medicines in shops and pharmacies without needing a prescription
- only use these medicines for a short time and to help with your symptoms. You should follow the instructions for use in the Patient Information Leaflet (PIL) and package labelling which comes with the medicine and to not exceed the daily recommended dose and to take note of the minimum time interval between doses
- do not use these medicines for more than 5 consecutive days
- if you use these medicines for longer than the recommended duration, your nose may become blocked again, and you may get other problems such as runny nose, sneezing, itching and irritation on the inside of the nose or your body can stop responding to the medicine
- these side effects may make you feel like you need to keep using the medication to manage your symptoms – talk to a healthcare professional if you are having trouble stopping the medication, or

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are using for longer or more than recommended

- contact your doctor if your symptoms worsen or you do not feel better after 5 days, as you may need a different treatment
- do not use xylometazoline or oxymetazoline together or with other oral and nasal forms of medicines used to treat a blocked nose, such as pseudoephedrine, phenylephrine or ephedrine
- it is important to read the PIL that comes with your medicine and information on the outer packaging and to talk to a healthcare professional if you experience side effects

Background

Review of rebound congestion, rhinitis medicamentosa, and tachyphylaxis with xylometazoline and oxymetazoline

Xylometazoline and oxymetazoline are sympathomimetic medicines used for the symptomatic relief of nasal and sinus congestion associated with the common cold, sinusitis, and allergic rhinitis in adults and children 6 years and above. They are also used for the treatment of symptoms of flu in adults and children 12 years and above. Xylometazoline is approved for use as a single active substance or in fixed dose combinations with dexpanthenol and ipratropium bromide. Oxymetazoline is approved for use as a single active substance only.

There have been reports of rebound congestion, rhinitis medicamentosa, and tachyphylaxis especially with prolonged or extended use. A review of the available evidence, including the assessment of cumulative reporting of adverse drug reaction reports, was considered by the Cardiovascular, Respiratory, Renal and Allergy Expert Advisory Group (CDRRA EAG) and the Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM). The EAGs recommended changing the maximum duration of use from 7 days to 5 days in adults and children 12 years and above to align duration of use across all patients for whom these medicines are indicated. The EAGs also recommended updating the Summary of Product Characteristics (SmPC) and PIL to highlight that these medicines are intended for short term use only and that repeated and/or prolonged use can increase the risk of side effects. Additionally, the outer package labelling will also be updated to emphasise the recommended duration of use. The product information will be transitioning over the next few months.

About rebound congestion, rhinitis medicamentosa, and tachyphylaxis

The terms 'rebound congestion' and 'rhinitis medicamentosa' are often used interchangeably, as both describe nasal congestion resulting directly from heavy or prolonged use of nasal decongestant sprays containing xylometazoline and oxymetazoline. Although both conditions cause nasal congestion, they differ in their duration and symptoms.

Rebound congestion is a temporary response that occurs when nasal passages become swollen due to excessive use of nasal decongestant sprays containing xylometazoline and oxymetazoline. The condition is characterised by a 'rebound effect', in which the nasal passages become more congested after the effect of the medication wears off.

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Rhinitis medicamentosa is a chronic condition that develops through prolonged or extended use of nasal decongestant sprays. With continued use of these medicines, rebound congestion can worsen and progress to rhinitis medicamentosa, the most serious of these reported effects. The condition is characterised by severe nasal congestion together with visible changes to the nasal mucosa and other internal nasal structures. Additional symptoms may include itchy nasal passages, sneezing, and a runny nose. In severe and untreated cases, this can result in irreversible structural changes within the nasal passages that may require surgical intervention to correct. Unlike other types of rhinitis which may affect the ear, throat, and eyes, rhinitis medicamentosa is confined to the nasal passages. Rebound congestion and rhinitis medicamentosa can lead to a cycle of overuse and dependence on nasal decongestants, where users can feel the need to use more medication to achieve relief.

For both conditions, patients typically fully recover within 3 months with early recognition and treatment. Treatment involves gradually reducing use of the nasal decongestants. Stopping abruptly is not always recommended as this can worsen symptoms of the nasal congestion. Alternative treatment may be required.

Tachyphylaxis refers to an acute sudden decrease in response to a drug after its administration, which leads to rapid onset of drug tolerance. In the context of nasal decongestant sprays and drops, it is a condition where onset begins after a few doses, although the effects of this become apparent after more than 5 days continuous use. It is characterised by a swift decrease in the effectiveness of a medication, which has significant clinical implications as the symptoms of congestion return resulting in the user increasing the frequency and/ or duration of use of their medicine to achieve symptomatic relief from their nasal congestion.

NICE Clinical Knowledge Summaries

For allergic rhinitis, NICE Clinical Knowledge Summaries recommend intranasal corticosteroids and antihistamines – either alone or combined – as first-line therapy for allergic rhinitis, alongside self-management strategies. Intranasal decongestants like xylometazoline should only be considered for short-term use when symptoms persist despite regular corticosteroid treatment or in cases of sudden, severe congestion. While xylometazoline and oxymetazoline can be used for allergic rhinitis, they are not a first-line option and prolonged use should be avoided, as adherence to limits on the stated maximum duration of use can be challenging for some patients.

For common cold, nasal decongestants containing xylometazoline or oxymetazoline are one of the over-the-counter products for the management of nasal congestion recommended within NICE Clinical Knowledge Summaries for adults and children over 6 years of age. However, the guidance has highlighted that prolonged use may cause rebound congestion, and in severe cases, rhinitis medicamentosa.

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/nasal-decongestant-sprays-and-drops-containing-xylometazoline-hydrochloride-slash-oxymetazoline-hydrochloride-increased-risk-of-rebound-congestion-rhinitis-medicamentosa-and-tachyphylaxis-with-overuse>

In Hong Kong, there are 16 registered pharmaceutical products containing xylometazoline hydrochloride and 13 registered pharmaceutical products containing oxymetazoline hydrochloride. All products are over-the-counter medicines except one containing steroid, which is a prescription-only medicine. So far, the Department of Health (DH) has received 19 cases of adverse drug reaction reports with regard to xylometazoline, of which 1 case was reported as rhinitis medicamentosa and none were reported as rebound congestion or tachyphylaxis. The DH has not received any cases of adverse drug reaction reports with regard to oxymetazoline. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Clive CHAN)

for Assistant Director (Drug)