Different nasal spray preparations should not be mixed together. Quality, Safety and Efficacy of such preparations cannot be guaranteed

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It has been brought to our attention that a particular prescription for an extemporaneous preparation of Nasacort Spray mixed with Hysan spray is being prescribed on a regular basis.

Information on the medicinal products

- Hysan Spray contains the active ingredient xylometazoline (an alpha-sympathomimetic agent). Xylometazoline has vasoconstrictive properties and effects decongestion of the nasal mucosa. Hysan spray is indicated for short-term treatment to reduce the swelling (congestion) of the nasal mucosa.

- Nasacort Nasal Spray contains active ingredient triamcinolone acetonide (a potent corticosteroid). Triamcinolone acetonide and other corticosteroids are very effective in the treatment of allergic condition. Nasacort is indicated for the treatment of symptoms of seasonal and perennial allergic rhinitis

The following products are authorised in Malta.

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Xylometazoline Hydrochloride 1 milligram/ millilitre	Hysan Adults Nasal Spray	Nasal Spray, Solution	OTC	AA063/00501	Ursapharm Arzeneitmittel GmbH & CO. KG
Xylometazoline Hydrochloride 0.5 milligrams/ millilitre	Hysan Paediatric Nasal Spray	Nasal Spray, Solution	OTC	AA063/00801	Ursapharm Arzeneitmittel GmbH & CO. KG
Triamcinolone acetonide 0.055% weight/weight	Nasacort Allergy 55mcg/dose Nasal Spray	Nasal Spray, Suspension	OTC	AA082/05901	Sanofi Malta Limited
Triamcinolone acetonide 55 micrograms/dose	Nasacort	Nasal Spray, Suspension	POM	MA082/01701	Sanofi Malta Limited

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Information about the issue and the potential concerns

The particular prescription calls for forcing open a bottle of Hysan and adding a prescribed volume of Hysan solution into a full bottle of Nasacort suspension. The preparation is being prescribed to patients suffering from rebound congestion (rhinitis medicamentosa) as to gradually reduce the patients' dependence on topical sympathomimetic decongestants. Reactive hyperaemia of the nasal mucosa (rhinitis medicamentosa or rebound congestion) is caused by permanent use and overdosing of decongestive sympathomimetic nasal preparations containing xylometazoline and oxymetazoline. Atrophy of the nasal mucosa may also occur with prolonged use.

The practice of extemporaneous mixing of these products presents several potential concerns, including;

- A risk of non-standardised formulations, a lack of uniformity in dosing, potential formulation failure due to incompatibility of active substance and/or excipients, possible microbiological contamination and a lack of stability information.
- The conditions, environment and processes used to prepare this combination are not controlled.
- Adverse drug reactions arising from such a practice will be difficult to evaluate because it is not possible to ascertain if it is the active ingredients or the properties of the prepared mixture which is causing the reaction.

The Medicines Authority is not aware of compatibility studies available on this particular combination of products being mixed and for this reason the Medicines Authority is of the opinion that quality, safety and efficacy of this preparation cannot be guaranteed.
Furthermore, suitable licensed formulations are available to treat patient suffering from rebound congestion (rhinitis medicamentosa) and hence this practice should be avoided.

In Malta

For Healthcare Professionals

Healthcare professional should always keep in mind stability related issues when prescribing extemporaneous mixtures for individual patients for which no data is available. Prescribers should refer to the Summaries of Product Characteristics for more information.

If Nasacort spray, Hysan spray, or a combination of any topical nasal preparations need to be used concurrently then these should be administered separately. Patients should be advised to leave some time between administrations of the different products. These principles apply to other topically applied preparations.

Advice for Patients

- Patients are reminded that topical sympathomimetic decongestants are indicated for short term use and should not be used for longer than 7 days. The recommended dose should not be exceeded.
- Patient suffering from frequent or persistent nasal congestion should consult their doctor for advice
- Patients are reminded that Nasacort spray does not have an immediate effect on allergic signs and symptoms. An improvement in some patients symptoms may be seen within the first day of treatment with Nasacort and relief may be expected in 3 to 4 days.
- In order to help achieve the maximum benefits provided by the medications, patients should consult the package leaflet for instructions on how to apply the nasal spray; this is applicable to all nasal sprays.
- Patients are encouraged to always consult the patient information leaflet especially when using over the counter medicinal products
- Patients who have any questions should speak to their doctor or pharmacist.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on nasal decongestants for topical use. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: **http://www.medicinesauthority.gov.mt/adrportal**) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to **postlicensing.medicinesauthority@gov.mt** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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