

April 2023

Naseptin Nasal Cream: Caution advised when prescribing and dispensing due to reformulation to remove allergen

Dear Healthcare professional,

Alliance Pharmaceuticals Ltd, in agreement with the Medicines and Healthcare product Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- **Naseptin Nasal Cream has undergone a formulation change, the excipient Arachis oil (peanut oil) has been removed.**
- **Both the original formulation containing Arachis oil and the revised formulation without Arachis oil will be in circulation in the supply chain until November 2025.**
- **Extra care regarding patient allergy status must be taken when prescribing and dispensing this product during this transition period.**
- **Verify if the patient has an allergy to peanut or to soya – if so, take care to dispense only the Arachis oil-free formulation.**

Background on the safety concern

Naseptin Nasal Cream, containing the active ingredients chlorhexidine dihydrochloride and neomycin sulfate, is indicated for treatment of nasal infection with Staphylococci, and eradication of Staphylococci carriage from the nasal passages. It is for nasal application only.

The original formulation contains the excipient Arachis oil (peanut oil), which can induce an allergic response in some patients. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid the original Naseptin formulation.

This important information regarding the original formulation is available as a boxed warning in section 2 of the Package leaflet, and on the product's carton and tube.

Naseptin Nasal Cream has been reformulated by replacing the excipient Arachis oil with medium-chain triglycerides, to minimise the risk of allergic reactions in these patients.

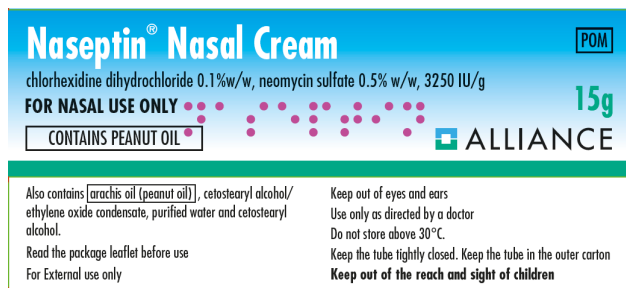
The new Arachis oil-free formulation is planned to reach the supply chain as of 21st April 2023.

The last batch of the original formulation will expire on 31 October 2025. During the transition period, both formulations may be available for use.

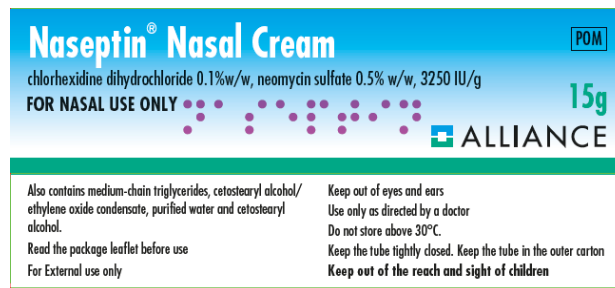
Extra care must be taken when prescribing and dispensing Naseptin Nasal Cream during this transition period. The prescriber/dispenser must be aware of the allergy status of each patient and ensure the formulation patients receive is appropriate.

The labelling on the original formulation contains a peanut oil boxed warning, the new formulation does not (see images of the cartons provided below).

Original formulation:



New formulation:



Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

You can report via:

- the Yellow Card website <https://yellowcard.mhra.gov.uk/>
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point

Marketing authorisation holder	Product	Contact details
Alliance Pharmaceuticals Limited	Naseptin Nasal Cream	Address: Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB Telephone: +44 (0)1249 466 966 E-mail: medinfo@alliancepharma.co.uk

Yours sincerely,

Isabel Carrillo Casas

Qualified Person for Pharmacovigilance

Alliance Pharmaceuticals Ltd