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What is the role of nasal irrigations and when are they used?

Chronic rhinosinusitis is a condition that occurs when the lining of the sinuses becomes infected, irritated, or inflamed. The prevalence of rhinosinusitis globally is estimated to be as high as 12% and incidence in the US is thought to be 1-5%.^{1,2} To be considered chronic, rhinosinusitis must have occurred for at least 12 consecutive weeks.² Conventional treatments may include irrigations with saline, intranasal corticosteroid nasal sprays, short courses of oral steroids, or even oral antibiotics.² When conventional treatments are not successful, alternatives such as corticosteroids for nasal irrigation are sometimes considered.² One study of 12 patients suffering from chronic rhinosinusitis with nasal polyps and asthma treated patients with 0.5mg budesonide in 250ml normal saline. Half the volume was applied in each nostril twice daily for six months. The treatment was noted to be effective and to reduce the need for oral steroid intake.³ In addition to steroids, antibiotics are also sometimes used topically for nasal irrigation. One review of 58 patients suffering from chronic rhinosinusitis tested the utility of topical antibiotics based on susceptibility of the microbe to various antimicrobials. The antibiotics selected for these patients included tobramycin 100mg/100ml, vancomycin 200mg/100ml, levofloxacin 100mg/100ml, mupirocin 15mg/100ml, gentamicin 80mg/100ml, ceftriaxone 200mg/100ml, and ceftazidime 600mg/100ml. Patients irrigated each nostril with 50ml twice daily for 30 days. The study found that topical antibiotics resulted in improved symptom severity and significantly improved endoscopic appearance. Additionally, 72% of patients treated with topical antibiotics had negative posttreatment culture results.⁴ Anti-fungal nasal irrigations, such as those containing amphotericin B at 100mcg/ml or 200mcg/ml, have also been evaluated for chronic rhinosinusitis, however, current data has not noted benefit over normal saline nasal irrigation.⁵ Though data is currently limited for many of these irrigation

treatments, existing information supports potential utility for some of these active pharmaceutical ingredients (APIs) delivered topically nasally in those who are unable to find resolution with commercially available options.

Are nasal sprays and irrigations required to be sterile?

Under current and proposed USP <795>, nasal sprays and irrigations are not required to be sterile. Proposed USP <795> guidelines lay out under section 1.1 (Scope) examples of what may be considered as a compounded nonsterile preparation (CNSP):

- Solid oral preparations
- Liquid oral preparations
- Rectal preparations
- Vaginal preparations
- Topical preparations (i.e. creams, gels, and ointments)
- Nasal and sinus preparations intended for local application (i.e. nasal sprays and nasal irrigation)
- Otic preparations (excluding use in perforated eardrums)

How are nasal irrigations dispensed?

Nasal irrigations may be dispensed as premade liquids in vehicles safe for application to the sinuses, such as sterile water for irrigation, USP, or sodium chloride 0.9% for irrigation, USP.^{1,3,4} For ingredients that are subject to rapid degradation in aqueous environments or for volumes that are difficult or impractical to dispense or ship, a dry form such as a capsule with an appropriate dispersible and soluble capsule filler could be considered. Capsules for nasal irrigation are dispensed to the patient who then opens them into appropriate solution for nasal irrigation and mixes prior to application. Dry powder dosage forms such as capsules allow for an extended beyond use date (BUD) per current and proposed USP <795> guidelines and are more easily transported by the pharmacy and patient compared to large volumes of premade irrigation solution.

What is DispersaPro and how does it work?

DispersaPro is a micronized powder excipient designed to assist in the delivery of various APIs for non-sterile irrigation applications. Fagron DispersaPro powder contains poloxamers, which have been found in some studies to help disperse and solubilize poorly soluble APIs.⁷ It also contains xylitol, an ingredient that has been studied for its potential utility against biofilms.⁸ DispersaPro offers an anhydrous alternative for delivery of APIs with unknown or poor stability in aqueous vehicles, allowing patients to open capsules or packets containing DispersaPro immediately prior to use and disperse the powder in an aqueous vehicle for non-sterile irrigation applications, such as nasal irrigation.

Sources:

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