PRESERVATIVE-FREE OPHTHALMIC COMPOUNDING

Prescriber Reference Guide · The Medicine Shoppe, York PA

Unit-dose vials · BAK-free formulations · USP 797 compliant · Same-day / next-day turnaround

Program Overview

The Medicine Shoppe compounds preservative-free ophthalmic preparations in our USP 797-compliant sterile suite, dispensed as 10 × 1 mL single-use vials. This format eliminates benzalkonium chloride (BAK) and other preservative exposure entirely — a clinically meaningful advantage for patients on chronic ophthalmic therapy, those with ocular surface disease, and post-surgical patients with compromised epithelium.

Each vial is sterile-filled, sealed, and labeled individually. One vial per eye, per dose. No contamination risk, no preservative accumulation, no multi-dose bottle degradation concerns.

Why Preservative-Free Matters Clinically

- BAK disrupts the tear film lipid layer and damages corneal epithelial tight junctions with chronic exposure
- Preservative toxicity is cumulative — patients on multiple preserved drops (glaucoma regimens, post-op protocols) face compounding risk
- BAK-related ocular surface disease mimics and worsens dry eye, complicating diagnosis and treatment response
- Preservative-free formulations are the standard of care for patients with dry eye disease, OSD, or frequent dosing requirements
- Unit-dose vials eliminate the multi-dose bottle contamination risk that contributes to post-surgical infections
- Patient adherence improves substantially when drops cause less irritation and stinging

Compounded Preparations — Formulary

All preparations below are available as sterile, preservative-free ophthalmic drops dispensed in 10 × 1 mL single-use vials. Custom concentrations available on request.

Preparation	Concentration	Category	Primary Use
Timolol	0.25%, 0.5%	Beta-blocker	IOP reduction in glaucoma and ocular hypertension
Dexamethasone Sodium Phosphate	0.1%	Corticosteroid	Post-surgical inflammation; anterior segment disease
Methylprednisolone	1%	Corticosteroid	Ocular anti-inflammatory; preservative-sensitive patients
Additional preparations	On request	Various	Contact our pharmacist — we compound to clinical specification

Custom Concentrations — If your required concentration is not listed, contact our compounding pharmacist directly. We prepare to your clinical specification.

Clinical Monographs

The following monographs provide prescribing rationale, dosing guidance, and the specific clinical case for preservative-free formulation for each preparation.

Timolol 0.25% and 0.5% — Preservative-Free Ophthalmic Drops

Rationale for Preservative-Free Formulation

Timolol is typically prescribed as a long-term, twice-daily therapy for glaucoma — meaning patients accumulate BAK exposure at every dose, every day, indefinitely. Chronic BAK exposure in glaucoma patients is well-documented to cause or worsen ocular surface disease (OSD), reduce goblet cell density, increase conjunctival inflammation, and ultimately compromise the surgical outcomes of future filtration procedures. The preservative-free formulation eliminates this risk entirely without altering efficacy.

Drug Class	Non-selective beta-adrenergic blocker
Concentrations	0.25% and 0.5%
Mechanism	Reduces aqueous humor production by blocking beta-adrenergic receptors in the ciliary body
Indication	Open-angle glaucoma; ocular hypertension; adjunct in angle-closure glaucoma
Typical Regimen	1 drop to affected eye(s) twice daily; some patients maintained on once daily
IOP Reduction	Typically 20–35% reduction from baseline; additive with prostaglandin analogues
Dispensing	10 × 1 mL preservative-free vials; room temperature; 28-day BUD; use each vial over 1–2 days
Systemic Cautions	Beta-blockade — use with caution in asthma, COPD, bradycardia, heart block, decompensated heart failure; counsel patients to occlude nasolacrimal duct after instillation to reduce systemic absorption

The OSD-Glaucoma Cycle

BAK-preserved timolol contributes to OSD → OSD worsens patient-reported symptoms → patients reduce adherence or request medication changes → IOP control deteriorates. Preservative-free timolol breaks this cycle. Multiple studies demonstrate significantly better ocular surface indices, lower inflammatory markers, and improved adherence with preservative-free beta-blocker formulations compared to BAK-preserved equivalents.

Dexamethasone Sodium Phosphate 0.1% — Preservative-Free Ophthalmic Drops

Rationale for Preservative-Free Formulation

Post-surgical patients represent the highest-risk population for preservative toxicity — the corneal epithelium is already compromised by surgical incisions, irrigation, and instrumentation. Introducing BAK-preserved drops during the healing phase adds a chemical insult to a tissue trying to recover. Preservative-free dexamethasone is the preferred choice for

post-operative anti-inflammatory therapy, particularly following cataract surgery, corneal procedures, and any surgery involving the ocular surface.

Drug Class	Corticosteroid — glucocorticoid receptor agonist
Concentration	0.1% (sodium phosphate, water-soluble)
Mechanism	Inhibits phospholipase A2 and downstream arachidonic acid cascade; suppresses prostaglandin and cytokine production
Indications	Post-operative inflammation (cataract, corneal, strabismus surgery); anterior uveitis; corneal graft rejection prophylaxis; allergic keratoconjunctivitis
Typical Regimen	Post-op: 1 drop 4× daily, taper over 4–6 weeks per protocol; uveitis: frequency per severity
Monitoring	IOP monitoring mandatory beyond 2 weeks — steroid response occurs in ~30% of patients; screen for PSC cataract with prolonged use
Dispensing	10 × 1 mL preservative-free vials; room temperature; 28-day BUD; use each vial over 1–2 days
Notes	Sodium phosphate formulation preferred where water solubility matters clinically; shake gently before use

Post-Surgical Prescribing Note

For standard post-cataract surgery protocols, preservative-free dexamethasone 0.1% is fully interchangeable with commercial preserved equivalents on a drop-for-drop basis. The clinical rationale for the preservative-free formulation is strongest in the first 2–4 weeks post-operatively when the epithelium is most vulnerable. Patients with pre-existing dry eye disease or OSD benefit throughout the taper.

Methylprednisolone 1% — Preservative-Free Ophthalmic Drops

Rationale for Preservative-Free Formulation

Methylprednisolone 1% is not available in any commercial ophthalmic formulation — it must be compounded. It offers a potent corticosteroid option for patients who are intolerant of or have not responded adequately to dexamethasone or prednisolone acetate, or where the prescriber prefers a water-soluble glucocorticoid without the suspension-related variability of prednisolone acetate. The preservative-free unit-dose format is the only clinically appropriate way to dispense this preparation.

Drug Class	Corticosteroid — glucocorticoid receptor agonist
Concentration	1%
Mechanism	Broad anti-inflammatory action via glucocorticoid receptor; inhibits NF-κB and downstream inflammatory mediator production
Indications	Anterior uveitis; post-operative inflammation; allergic conjunctivitis; episcleritis; patients intolerant of commercial corticosteroid drops
Typical Regimen	1 drop 4–6× daily; taper over 4–6 weeks depending on indication and response
vs. Other Steroids	Water-soluble formulation; no need to shake (unlike prednisolone acetate suspension); more consistent dosing per drop
Monitoring	IOP monitoring required beyond 2 weeks; steroid responder assessment as with all ophthalmic corticosteroids
Dispensing	10 × 1 mL preservative-free vials; room temperature; 28-day BUD; use each vial over 1–2 days
Notes	No commercial equivalent — compounding is the only source; contact pharmacy before prescribing if questions about formulation

Corticosteroid Selection Summary

All three compounded corticosteroid preparations — dexamethasone 0.1%, methylprednisolone 1% — are glucocorticoids with broadly similar anti-inflammatory efficacy at these concentrations. Selection is driven by formulation preference, patient tolerability, prior response, and clinical setting. Dexamethasone sodium phosphate is first-line for most post-surgical protocols. Methylprednisolone 1% is a compelling option for patients with sensitivity to commercial preparations or who require a water-soluble alternative without suspension variability.

Dispensing, Storage & Beyond-Use Dating

Format	10 × 1 mL sterile preservative-free vials per dispensing unit
Sterility	Compounded in ISO-classified clean room under USP 797 standards
Beyond-Use Date	28 days from date of compounding; labeled on each vial and outer packaging
Storage	Room temperature (59–77°F / 15–25°C); protect from light; do not freeze

Usage	Each 1 mL vial contains enough solution for multiple doses; use over 1–2 days, then discard
Refills	Contact pharmacy 5–7 days before supply runs out; same-day or next-day preparation available

Ordering & Contact Information

All preparations require a valid prescription from a licensed prescriber. Patients may drop off, call, fax, or have their provider e-prescribe directly to us. Same-day or next-day preparation available for most orders.

How to Order

- By phone — call (717) 846-0500; ask for the compounding pharmacist; have patient name, DOB, preparation, concentration, and quantity ready
- By fax — send prescription to (717) 845-8767; include preparation, concentration, quantity, dosing instructions, and any clinical notes
- E-prescribe — select 'Compound' as medication type; specify preparation, concentration, and '10 × 1 mL preservative-free vials' in Sig/Comments field

USP 797 Compliance

All sterile ophthalmic preparations are compounded in our ISO-classified clean room under USP Chapter <797> standards. Environmental monitoring, personnel garbing and competency assessments, and sterility testing are conducted per USP 797 requirements. Documentation is available upon request for credentialing, hospital formulary review, or accreditation purposes.

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USP 797 Sterile Compounding
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