

Oral Suspending Vehicle



Available through your wholesaler or distributor.

ORA-Plus® is a unique suspending vehicle used to simplify the process involved in the extemporaneous compounding of oral suspensions. Medicated powder can be incorporated into ORA-Plus® to form elegant, uniform and physically stable suspensions.

Applications

ORA-Plus® will retain its suspending properties when diluted up to 50% with water, flavoring agents, syrups or alcohol. Its versatility makes it ideal for:

- Pediatric suspensions
- Geriatric suspensions
- Naso-gastric preparations

How to Use

ORA-Plus® can be used in a combination with any flavoring syrup, but it is specially formulated to complement Padagis' ORA-Sweet®. ORA-Plus® and ORA-Sweet® can be combined in a 50/50 ratio to produce a pleasant tasting elegant suspension.

Properties

ORA-Plus® is an aqueous-based vehicle consisting of a synergistic blend of suspending agents that have a high degree of colloidal activity. The suspending agents form a structured, gel-like matrix which suspends particles and allow for little settling. ORA-Plus® is buffered to a slightly acidic pH to help reduce degradation of medicinal agents through oxidation. An anti-foam agent is incorporated in ORA-Plus® to allow for vigorous shaking with minimal foam.

Contains:

Purified water, microcrystalline cellulose, carboxymethylcellulose sodium, xanthan gum, carrageenan, calcium sulfate, trisodium phosphate, citric acid and sodium phosphate as buffers, dimethicone antifoam emulsion. Preserved with methylparaben and potassium sorbate.

Specifications

Appearance: Translucent, milky white, thixotropic liquid

pH range: 4.0 - 4.5

Taste: Very bland taste (no sweeteners or flavors)

Viscosity: Thixotropic. Range 400 - 6700 cps at 25°C via Brookfield viscometer

Osmolality: Approximately 157 mOsm/kg

Compounding Examples



BACLOFEN 10 mg/mL, 120 mL¹

Baclofen 10 mg/tablet	120 tablets
ORA-Plus®	60 mL
ORA-Sweet®*	q.s. 120 mL

- Expiration 60 days
- Protect from light
- Shake well before using

DILTIAZEM HYDROCHLORIDE 12 mg/mL, 120 mL¹

Diltiazem HCl 90 mg/tablet	16 tablets
ORA-Plus®	60 mL
ORA-Sweet®*	q.s. 120 mL

- Expiration 60 days
- Protect from light
- Shake well before using

ENALAPRIL MALEATE 1 mg/mL, 120 mL²

Enalapril Maleate 20 mg/tablet	6 tablets
ORA-Plus®	60 mL
ORA-Sweet®*	q.s. 120 mL

- Expiration 60 days
- Protect from light
- Shake well before using

CAPTOPRIL 0.75 mg/mL, 134 mL¹

Captopril 100 mg/tablet	1 tablet
ORA-Plus®	67 mL
ORA-Sweet®*	q.s. 134 mL

- Expiration is 7 days at 25°C or 14 days at 4°C
- If ORA-Sweet® SF is used, expiration is 5 days at 25°C or 10 days at 4°C
- Protect from light
- Shake well before using

DIPYRIDAMOLE 10 mg/mL, 120 mL¹

Dipyridamole 50 mg/tablet	24 tablets
ORA-Plus®	60 mL
ORA-Sweet®*	q.s. 120 mL

- Expiration 60 days
- Protect from light
- Shake well before using

FLECAINIDE ACETATE 20 mg/mL, 120 mL¹

Flecainide Acetate 100 mg/tablet	24 tablets
ORA-Plus®	60 mL
ORA-Sweet®*	q.s. 120 mL

- Expiration 60 days
- Protect from light
- Shake well before using

General Directions for Compounding ORA-Sweet®*/ORA-Plus® Suspensions

ORA-Sweet® and ORA-Plus® should be combined in a 50/50 ratio to achieve optimal formulation.

- Calculate the total amount of active ingredient and volume of solution needed to create a suspension of the proper concentration. (Calculations are provided in the examples to the left.) *It may be wise to add approximately 10% overage for compounding losses.*
- Crush tablets with a mortar and pestle to a fine powder. If the compound is already in the powder form, use the mortar and pestle to smooth out the powder.
- Add a small amount of **ORA-Plus®** and triturate to a thick, smooth paste. Add the remainder of the **ORA-Plus®** by geometric dilution. *The amount of ORA-Plus® should be 50% of the total solution.*
- Bring the suspension to a final volume using **ORA-Sweet®***. Mix briefly with a mortar and pestle until a uniform suspension is formed.
- Dispense in a tight, light resistant amber bottle with appropriate labeling.
- Label with an expiration date. *If the stability of the medication in an oral suspension or syrup is unknown, conservative dating is suggested.*
- Depending on the medicinal agent used, label containers “Shake Well Before Using”, “Protect From Light”, and “Keep Refrigerated”.

*ORA-Sweet® may be substituted with ORA-Sweet® SF. Both products may be used in a 1:1 ratio with ORA-Plus®.

¹American Journal of Health-System Pharmacists 1996; 53:2179-84.

²American Journal of Health-System Pharmacists 1998; 55:1915-20.

Contraindications

ORA-Plus® is contraindicated in persons who have shown hypersensitivity to any of the listed ingredients.

DISCLAIMER:

All information presented is intended to demonstrate the application of Padagis® vehicles in compounding. The information and examples provided in this paper have not been evaluated by the Food and Drug Administration and are provided for educational purposes only. Any information and examples provided are not intended to replace the advice of a physician or take the place of good pharmaceutical compounding practices. The preparation, dispensing, and administration of pharmaceuticals is the responsibility of licensed medical professionals and must adhere to current pharmaceutical compounding requirements and lawful practice of medicine. Padagis® assumes no liability for any injury and/or damage to persons from use of any information and/or examples contained in this document. Padagis® does not warrant against infringements of patents of third parties by reason of any uses made of the vehicles in combination with other material or in the operation of any process. Vehicle purchasers assume all risks of patent infringement by reason of any such use, combination or operation. Before compounding any prescription drug with Padagis® vehicles, please review the full prescribing information of the prescription drug for important safety information and limitations of use.