# **ORA-Plus®**

### **Oral Suspending Vehicle**



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 Perrigo's ORA-Sweet<sup>®</sup>. 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

Available through your wholesaler or distributor.



# **ORA-Plus**®

## **Compounding Examples**



#### BACLOFEN 10 mg/mL, 120 mL1

120 tablets Baclofen 10 mg/tablet 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 mL<sup>1</sup>

Diltiazem HCI 90 mg/tablet ORA-Plus ORA-Sweet\*

16 tablets 60 ml q.s. 120 mL

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

#### ENALAPRIL MALEATE 1 mg/mL, 120 mL<sup>2</sup>

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

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

#### CAPTOPRIL 0.75 mg/mL, 134 mL<sup>1</sup>

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 mL<sup>1</sup>

Dipyridamole 50 mg/tablet 24 tablets **ORA-Plus** 60 mL ORA-Sweet\* g.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
- Add a small amount of **ORA-Plus** and triturate to a thick, <u>smooth</u> 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. <sup>1</sup>American Journal of Health-System Pharmacists 1996; 53:2179-84.

<sup>2</sup>American 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.

All information presented is intended to demonstrate the application of Perrigo 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. Perrigo assumes no liability for any injury and/or damage to persons from use of any information and/or examples contained in this document. Perrigo 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 Perrigo vehicles, please review the full prescribing information of the prescription drug for important safety information and limitations of use

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