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.

NDC #	Size
0574-0303-16	473 mL (one pint)

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[®]. 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.

Ingredients

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 1300 - 6700 cps at

25°C via Brookfield viscometer

Osmolality: Approximately 157 mOsm/kg



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ORA-Plus®

Formulating & 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 mL¹

Diltiazem HCI 90 mg/tablet 16 tablets ORA-Plus 60 mL ORA-Sweet* a.s. 120 mL

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

ENALAPRIL MALEATE 1 mg/mL, 120 mL²

6 tablets Enalapril Maleate 20 mg/tablet **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 100 mg/tablet ORA-Plus 60 mL ORA-Sweet*

- Expiration 60 days
- Protect from light

FLECAINIDE ACETATE 20 mg/mL, 120 mL1

24 tablets q.s. 120 mL

- · 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. 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.

All information presented is intended to demonstrate the application of Perrigo vehicles in compounding. Perrigo products are sold on the understanding that purchasers will make their own determinations as to the suitability, safety and effectiveness of their applications. The uses presented by Perrigo are only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by Perrigo Pharmaceuticals. Perrigo Pharmaceuticals 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, and purchasers assume all risks of patent infringement by reason of any such use, combination or operation.



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