



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

17.10.2022

Version:

2.0

9134-ORA PLUS

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Ora Plus 473 ml

Bulk code: 9134

Internal code: 49491

1.2 Synonyms

No information available.

2. DESCRIPTION

Appearance: Thixotropic liquid.

Colour: Milky white, translucent.

Odour/Taste: Very mild taste.

3. COMPOSITION/INFORMATION ON COMPONENTS

Purified water, microcrystalline cellulose, sodium carboxymethyl cellulose, xanthan gum, carrageenan, calcium sulphate, trisodium phosphate, citric acid and sodium phosphate as buffers, dimethicone antifoam emulsion. Preserved with methylparaben and potassium sorbate. (No sweeteners or flavourings).

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Osmolality: 157 mOsm/kg

5. PROPERTIES/USES

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

- paediatric suspensions
- geriatric suspensions
- nasogastric preparations

Ora-Plus is a water-based sweetened vehicle consisting of a synergistic mixture of agents with a high degree of colloidal activity. The suspending agents form a structured, gel-like matrix with suspended particles and allow little sedimentation.

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Ora-Plus is buffered at a slightly acidic pH to help reduce the degradation of medicinal agents through oxidation.

An anti-foaming agent is added into Ora-Plus to allow for vigorous stirring with minimal foam.

Modus operandi:

- Calculate the total amount of active ingredient and the volume of solution needed to create a suspension at the appropriate concentration (it may be desirable to add around a 10% surplus to compensate for losses arising from the formulation process).
- Grind the compound to a fine powder using a mortar.
- Add a small amount of ORA-Plus and mix until a thick, smooth paste is obtained. Add the rest of the ORA-Plus by geometric dilution. The amount of ORA-Plus should be 50% of the total solution.
- Bring the suspension to the final volume using ORA-Sweet*. Mix in a mortar until an even suspension forms.
- Dispense into an airtight, light-resistant amber bottle with proper labelling.

6. DOSAGE

At 50:50 combined with Ora-Sweet to form a suspension of optimal characteristics.

7. REMARKS**STORAGE:**

Store at room temperature, in a cool, dry place, away from sunlight, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The above-mentioned products are not made and do not come into contact with human or animal products. The ingredients, excipients, adjuvants, components and reagents used to manufacture the above elements do not come into contact with bovine, ovine or caprine materials during the manufacturing process. Therefore, the above-mentioned products are free of any form of bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE). They comply with the applicable regulations and guidance on minimising the risk of



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transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3).

GMOs:

May contain one or more ingredients that are not GMO-free, therefore we cannot guarantee the absence of GMOs.

ALLERGENS:

According to the manufacturer, all raw materials used to produce the above products have been certified as free of the following allergens:

- Crustaceans
- Eggs
- Fish
- Gluten
- Milk and dairy products
- Peanuts
- Soy products
- Tree nuts

COLOURANTS:

ORA-Plus® does not contain contains colourants.

CORN:

ORA-Plus is not expected to contain corn allergens.