



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

9133-ORA-BLEND<sup>®</sup> 473 ML

## 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

### 1.1 Identification of the substance or preparation

Name: Ora-Blend<sup>®</sup> 473 ml

Bulk code: 9133

Internal code: 49491

### 1.2 Synonyms

No information available.

## 2. DESCRIPTION

Appearance: Opaque liquid

Colour: Pink

Odour/Taste: Sweet, of berries, citrus

## 3. COMPOSITION/INFORMATION ON COMPONENTS

Purified water, sucrose, glycerine, sorbitol, flavour, 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.

## 4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Osmolarity: 1665 mOsm/kg

## 5. PROPERTIES/USES

Oral use.

Ora-Blend<sup>®</sup> combines the suspending properties of Ora-Plus<sup>®</sup> with the flavouring agents of Ora-Sweet<sup>®</sup> and is ideal for paediatric and geriatric suspensions.

Ora-Blend<sup>®</sup> 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-Blend<sup>®</sup> 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-Blend<sup>®</sup> to allow for vigorous stirring with minimal foam.

#### General 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 active ingredient to a fine powder using a mortar.
- Add a small amount of Ora-Blend<sup>®</sup> and mix until a thick, smooth paste is obtained. Add the rest of the Ora-Blend<sup>®</sup> by geometric dilution.
- Mix briefly in the mortar until an even mixture is obtained.
- Dispense into an airtight, light-resistant amber bottle with proper labelling.

#### 6. DOSAGE

No information available.

#### 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



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comply with the applicable regulations and guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3).

#### **GMOs:**

Ora-Blend® contains sorbitol. Sorbitol is produced from corn syrup. The corn syrup supplier does not guarantee GMO-free products and does not perform an analysis to confirm the absence of GMO DNA protein. As such, it cannot be stated or guaranteed that Ora-Blend® is GMO-free as sorbitol is used as a vehicle in Ora-Blend®. The labelling of GMOs is not mandatory in accordance with Regulation (EC) 1830/2003 on the traceability and labelling of genetically modified organisms and the traceability of food and feed produced from genetically modified organisms.

#### **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-Blend® SF contains flavouring and therefore contains a small amount of FD&C Red 40 (Allura Red).

#### **CORN:**

Ora-Blend® contains sorbitol and therefore may contain corn by-products.