

## SUMMARY PRODUCT CHARACTERISTICS

### 1. Name of the medicinal product

Anginovag

### 2. Qualitative and Quantitative Composition

Each 100 mL contains:

**Active ingredient:**

Dequalinium chloride 0.100g; Tyrothricin 0.400g; Hydrocortisone acetate 0.060g;  
Lidocaine hydrochloride 0.100 g; beta-Glycyrrhetic acid 0.060 g

### 3. Pharmaceutical Form

Oromucosal spray

Is supplied in bottles containing 10 mL of solution

### 4. Clinical Particulars:

#### 4.1 Therapeutic Indications:

-Preventive and curative therapy of buccopharyngeal affections: ulcers, aphthae, stomatitis, laryngitis, glossitis, amygdalitis, pharyngitis.

#### 4.2 Posology and method of administration:

**Posology:**

Attack dose: 1-2 applications each 2-3 hours.

Maintenance or preventive therapy: 1 application each 6 hours.

**Method of administration:**

It is recommended to place the flask in upright position with the cannula pointing towards the place of application, but without introducing it completely in the mouth.

Press the upper part of the cap.

#### 4.3 Contraindications

It must not be administered to patients with known allergy to any ingredient.

#### 4.4 Special warnings and precautions for use:

It is advisable not to administer Anginovag in conjunction with other topical Treatments

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Can be interacted by other oral topical products.

#### **4.6 Pregnancy and Lactation**

Controlled studies in woman or in the animal are not available.

Nevertheless Anginovag is marketed in a flask provided with a dosing valve that permits the application of the adequate quantity of active ingredients with topical activity without systemic absorption.

Consequently it can be used during the pregnancy and lactation.

#### **4.7 Effects on the ability to drive and use machines**

Anginovag, does not produce any effect over the ability to drive and use of machines.

#### **4.8 Undesirable effects**

With not known frequency, blurred vision may occur (see also section 4.4).

#### **4.9 Overdose**

Given the scarce toxicity of the preparation, the appearance of poisonings is not foreseen, even in those cases having, accidentally, exceeded the therapeutical doses.

### **5. Pharmacological properties**

#### **ATC Code R02AA.**

Products for the throat. Topical Antiseptics.

#### **5.1 Pharmacodynamics**

The efficacy of Anginovag have been evaluated “in vivo” and “in vitro” tests.

Anginovag inhibits the growth of pathogen germs in both kinds of test.

Besides eliminate the pain immediately after the application and reduce the inflammation in a short time.

#### **5.2 Pharmacokinetics**

It have been not possible to make a classic pharmacokinetic study with Anginovag because the product does not produce suffice systemic levels of active ingredients to evaluate them.

#### **5.3 Preclinical safety data:**

Anginovag has a very low toxicity rate which confers it a broad safety margin.

The long-term administration does not show toxic effects, due to the exclusive topical action.

### **6. Pharmaceutical particulars:**

#### **6.1 List of Excipients**

Sodium saccharin

Propyleneglycol

Pineapple oil

Ethyl alcohol 96° q.s. 100 mL

## **6.2 Incompatibilities**

## **6.3 Shelf-life**

4 years.

## **6.4 Special precautions for storage**

Store at a temperature under 30° C

## **6.5 Nature and contents of container**

Polyethylene flask provide with an spray dosing valve.

Cardboard boxes on which are printed the composition, batch, date of expiry, route of administration and manufacturer.

## **7. Marketing Authorization Holder:**

Ferrer Internacional, S.A.  
Gran Via Carlos III, 94  
08028 Barcelona  
Spain

## **8. Marketing Authorization number:**

MA130/00101

## **9. Date of first Authorization/Renewal**

26<sup>th</sup> May 2006

## **10. Date of revision of the text:**

29<sup>th</sup> April 2020