SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ANGINOVAG Oromucosal spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per 1 ml :
Dequalinium chloride ..... 1,0 mg
Enoxolone..... 0,6 mg
Hydrocortisone acetate ..... 0,6 mg
Tyrothricin..... 4,0 mg
Lidocaine hydrochloride ..... 1,0 mg

Excipient(s) with known effect :
Propylene glycol 93,33 mg and ethanol 89,385 % v/v.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oromucosal spray solution.
Clear, colourless or slightly yellow solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Preventive and curative therapy of oropharyngeal affections:
Amygdalitis, pharyngitis, laryngitis, stomatitis, oral ulcers and aphthae, glossitis.

4.2 Posology and method of administration

Posology

Oropharyngeal use.

Adults and children over 13 years old
Attack dose: 1-2 applications every 2-3 hours.
Maintenance or preventive dose: One application every 6 hours.

Paediatric population

The safety and efficacy of Anginovag in children aged under 13 years old have not yet been established.

Method of administration

Open the mouth widely. Point the inhaler mouthpiece to the affected area (throat, mouth, tongue, etc, depending on the case).
Push the upper part of the cap from top to bottom up to the limit, keeping the bottle in upright position.
The bottle is supplied with a metering valve: each actuation up to the limit causes the regulated drug delivery.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Sporting people should be informed that this drug contains a component that can produce a positive analytical result in an anti-doping control.

Excipients
This medicine contains 93,33 mg propylene glycol in each ml.

This medicine contains 89,385 % ethanol, equivalent to almost 75 mg per application.

This medicine is harmful for those suffering from alcoholism.

Alcohol content to be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patientes with liver disease or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction

This medicament contains 89,385% v/v of ethanol in the final volume. This can modify or increase the effect of other medicaments..

4.6 Fertility, pregnancy and lactation

No clinical data on use in pregnancy and lactation are available

4.7 Effects on ability to drive and use machines

Anginovag has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

In some cases, depending on the peculiarities of the disease, ANGINOVAG may produce a local irritation that is usually temporary.

No other undesirable effect have been described at the recommended therapeutical doses.

4.9 Overdose

No case of overdose has been reported

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat preparations. ATC code: R02AA.

Anginovag combines in its formula active principles with antiinflamatory/analgesic and antibiotic actions having complementary and synergic actions:

- Thyrothricin is a topical antibiotic produced by Bacilus Brevis Dubos. It is active against many grampositive bacteria

- Dequalinium chloride is an antiseptic and disinfectant. It has shown activity against many bacteria, yeast and fungi

- Hydrocortisone acetate is an antiinflamatory substance targeting primary and secondary inflammation at the acute stage of the inflammatory process.

- Enoxolone is a potent inhibitor of the enzyme 11-hydrooxysteroid dehydrogenase. In concomitant application with hydrocortisone has shown to potentiate the activity of the hydrocortisone.

- Lydocaine hydrochloride is a local anaesthesic of the amide group. Acts by inhibition of the ionic refluxes required for initiation and conduction of nervous impulses.

5.2 Pharmacokinetic properties

There is very little pharmacokinetic information. However, and given the characteristics of the oropharyngeal use preparation, systemic absorption is very low.

5.3. Preclinical safety data

In rats, acute oral toxicity studies of the oral pharyngeal drug did not show signs of toxicity. No evidence of chronic toxicity has been observed, therefore, toxicity problems are not expected at the recommended doses**.**

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium, Propylene glycol, Pineapple oil and Ethanol 89.385% v/v.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 30º C

6.5 Nature and contents of container

20 ml plastic bottle sealed with a plastic metered dose pump containing 10 or 20 ml

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Ferrer Internacional, S.A.
Gran Vía Carlos III, 94
08028 Barcelona
SPAIN

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. **DATE OF REVISION OF THE TEXT**