Summary of Product Characteristics

1. Name of the medicinal product
SUPERIL LOZENGES
(Honey Lemon)

2. Qualitative and quantitative composition
Each Lozenge contains:
2,4-Dichlorobenzyl Alcohol……..1.2 mg
Amylmetacresol BP……...0.6 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Lozenges

4. Clinical particulars
4.1 Therapeutic indications
For the symptomatic relief of mouth and throat infections.

4.2 Posology and method of administration
Posology
Use the lowest dose for the shortest duration necessary to relieve symptoms.
Adults
One lozenge every 2-3 hours up to a maximum of 12 lozenges in 24 hours.
Elderly:
There is no need for dosage reduction in the elderly.
Children over 6 years old:
As above for adults.
Children under 6 years old:
Not suitable for children under 6 years. (See section 4.4)
Method of administration
For oral administration. To be dissolved slowly in the mouth.

4.3 Contraindications
Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use
Not to be given to children under 6 years.
If symptoms persist, have not improved, or have worsened after 3 days, consult a doctor or health care professional.
Important information about some of the ingredients of this medicine:
This medicine contains sucrose (1.44g per lozenge) and glucose (0.98g per lozenge). This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency should not take this medicine.
This medicine contains only very low levels of gluten (from wheat starch). It is regarded as ‘gluten-free’ and is very unlikely to cause problems if you have coeliac disease.
One lozenge contains no more than 19.52 micrograms of gluten.
If you have wheat allergy (different from coeliac disease) you should not take this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

This medicine contains fragrance with Citral, d-Limonene, Geraniol and Linalool.
Citral, d-Limonene, Geraniol and Linalool may cause allergic reactions.
This medicine contains Sulphites – Sulphur Dioxide (E220) (present in liquid glucose) which may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction
No clinically significant interactions are known.

4.6 Fertility, pregnancy and breastfeeding
Pregnancy
There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorbenzyl alcohol.
As with all medicines care should be taken when using this product in pregnancy and medical advice sought if necessary.
Brest-feeding
It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol or metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded.
Fertility
No data are available regarding the effects on fertility.

4.7 Effects on ability to drive and use machines
No or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
The list of the following adverse effects relates to those experienced with 2,4-dichlorobenzyl alcohol and amylmetacresol at OTC doses, in short term use.
Adverse events which have been associated with 2,4-dichlorobenzyl alcohol and amylmetacresol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (<1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity[ab1]
Gastrointestinal Disorders	Not known	Glossodynia[ab], oral discomfort[ab]

[a]2,4-dichlorobenzyl alcohol [b]amylmetacresol
[1]Hypersensitivity reactions may include rash, urticaria and angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing.

4.9 Overdose
Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic.

5. Pharmaceutical properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Throat Preparations; Antiseptics; ATC Code: R02AA03 Dichlorobenzyl alcohol
2,4-dichlorobenzyl alcohol and amylmetacresol are antiseptics and possess antibacterial (bactericidal and bacteriostatic), antifungal and antiviral properties as demonstrated in vitro.

When the two active agents are combined, a synergistic antibacterial action is observed leading to a reduced combined dose.
In-vitro studies demonstrated killing effects against some sore throat causing organisms such as Streptococcus pyogenes, Staphylococcus aureus, Haemophilus influenza and Moraxella catarrhalis, at 1 minute contact time. An overall reduction in the oral bacterial load was also seen in one in-vivo study.
In-vitro antiviral action against enveloped viruses including influenza A virus, para-influenza virus, respiratory syncytial virus, cytomegalovirus and coronavirus has also been observed for both AMC and DCBA as well as the combination of the two after 1-2 minutes contact.
In clinical studies, there was evidence that Superil lozenges led to reduction of throat soreness, and provided relief from pain and difficulty in swallowing, with onset of activity in 5 minutes and lasting for up to 2 hours. Significantly, more relief than non-medicated lozenge was also demonstrated for up to 3 days treatment. In one study, Superil lozenges have also been shown to significantly decrease post-operative throat soreness and hoarseness 20 minutes and 24 hours after intubation. A study in children (6-16 years) with acute and recurring chronic sore throat demonstrated a reduction in subjective and objective signs of sore throat over 3 days of treatment with Superil lozenges.
Superil Honey & Lemon lozenges contain flavours and honey whilst the base has a demulcent action providing throat soothing.

5.2 Pharmacokinetic properties
None available.

5.3 Preclinical safety data
None available.

6. Pharmaceutical particulars

6.1 List of excipients
Sucrose NF
Liquid Glucose BP
Citric Acid Monohydrate BP
Mentha Oil
Honey Flavour
Colour Sunset Yellow FCF
Caramel NF
Essence Lemon Oil
Purified Water BP

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C in a dry place. Keep out of reach of children

6.5 Nature and content of container

Blister of 12’s. 2 blisters are packed in pouch & packed in a Pack carton along with leaflet (2 x 12’s)

6.6 Special precautions for disposal and other handling
Not Applicable

7. Marketing Authorization Holder

UNIQUE PHARMACEUTICAL LABORATORIES
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Neelam center, B Wing, 4th floor, Hind cycle road,
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8. Marketing Authorization Number
06242/07791/REN/2021

9. Date of First Authorization/Renewal of the Authorization
Date of First Authorization: 24/07/2021

10. Date of revision of the text
27/07/2023