# SUMMARY OF PRODUCT CHARACTERISTICS

Y. S. P.

# Y. S. P. INDUSTRIES (M) SDN. BHD.
# SUMMARY OF PRODUCT CHARACTERISTICS

**PRODUCT NAME: HORF LOZENGES** Prepared on: 25 June 2018

1. **Name of the finished pharmaceutical product:**

   Horf Lozenges

2. **Qualitative and quantitative composition:**

   Chlorhexine Hydrochloride 5mg and Benzocaine 2mg

3. **Pharmaceutical form:**

   Tablet

4. **Clinical Particulars:**

   *4.1 Therapeutic indication:*

   For the prophylaxis of stomatitis, gangrenous stomatitis, pharyngitis, laryngitis, tonsillitis, gingivitis, post-tonsillectomy and post tooth extraction secondary bacterial infections. For the temporary local relief of pain associated with dental conditions and sore throats.

   *4.2 Posology and method of administration:*

   For prevention: 1 lozenge 4 – 5 times daily.

   Place the lozenge on the tongue and let it dissolve slowly for longer bactericidal action.

   To be dispensed on physician's prescription.

   *Method of administration*: Oral

   *4.3 Contraindication:*

   Horf Lozenges are contraindicated in patients with a history of hypersensitivity to Chlorhexidine and Benzocaine.

   *4.4 Special warnings and special precautions for use:*

   a) If symptoms persist, or irritation develops, discontinue medication and consult a physician.

b) Generally, the lozenges should not be used for self-medication longer than 2 days or in children younger than 3 years of age, unless directed by physician.

*4.5 Interaction with other FPPs and other forms of interaction:*

No information available.

*4.6 Pregnancy and lactation:*

No information available.

*4.7 Effects on ability to drive and use machines:*

No information available.

*4.8 Undesirable effects:*

Irritation or other adverse reactions such as dermatitis or photosensitivity are rare. Blackness or soreness of the tongue may occur, usually disappears when therapy is stopped. Methemoglobinemia has been reported to occur rarely in infants and children after administration.

*4.9 Overdose:*

Overdosage in human has not been reported to date.

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## 5. Pharmacological properties:

*5.1 Pharmacodynamic properties:*

a) Chlorhexidine is a biguanide disinfectant which is effective against a wide range of vegetative Gram-positive and Gram-negative bacteria, and it is more effective against Gram-positive than Gram-negative bacteria.

b) Chlorhexidine is absorbed onto the cell walls of microorganisms, which causes leakage of intracellular components. At low concentrations, Chlorhexidine is bacteriostatic; at higher concentrations, Chlorhexidine is bactericidal.

c) Because of its positive charge, Chlorhexidine is absorbed during oral rinsing on the surfaces of teeth, plaque, and oral mucosa, which have a net negative charge. Subsequently, the absorbed medication is gradually released from these sites by diffusion for up to 24 hours as the concentration of Chlorhexidine in the saliva decreases. This release provides a continuing bacteriostatic effect.

d) Benzocaine is a surface anesthetic of the ester type with low systemic toxicity. It is used in combination with Chlorhexidine for the local relief of pain associated with dental conditions, sore throats.

*5.2 Pharmacokinetic properties:*

This product contains Chlorhexidine and Benzocaine which is slowly dissolved in mouth and is poorly absorbed in the gastrointestinal tract for relief of sore throat for the treatment of various buccal infections. Pharmacokinetic studies indicate that approximately 30% of Chlorhexidine is retained in the oral cavity following rinsing and subsequently is slowly released into the oral fluid

*5.3 Preclinical safety data:*

No information available.

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## 6. Pharmaceutical particulars:

*6.1 List of excipients:*

a) Sodium Saccharin
b) Mannitol
c) Lactose Monohydrate
d) *l*-Menthol
e) Ammonium Monoglycyrrhizinate
f) Icing Sugar
g) Magnesium Stearate
h) Talc
i) Spearmint Oil
j) Peppermint Oil
k) Carboxymethylcellulose Sodium
l) Dimethylpolysiloxane
m) Ethanol
n) Isopropyl Alcohol
o) Purified Water

*6.2 Incompatibilities:*

No information available.

*6.3 Shelf life:*

2 years from the date of manufacturing.

*6.4 Special precautions for storage:*

Store at temperature below 30°C. Protect from light and moisture.

*6.5 Nature and contents of container:*

Strip Pack of 4's x 25

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*6.6 Instructions for use and handling <and disposal>:*

None has been mentioned.

**7. Marketing authorization holder:**

Name : Y. S. P. INDUSTRIES (M) SDN. BHD.

Address : Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi, 43000
Kajang, Selangor Darul Ehsan, Malaysia.

**8. Number(s) in the national register of finished pharmaceutical products:**

MAL 19940289AZ

**9. Date of first authorization / ~~renewal~~ of the authorization:** 20 November 2014

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

25 June 2018