# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

TIPTIPOT SIMICOL

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

SIMETHICONE 20 MG / 0.3 ML (66.67 MG / 1 ML)

For full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Drops

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Antiflatulent for relief of gripping pain, infant colic or wind due to swallowed air.

### 4.2. Posology and method of administration

Oral

Recommended Dosage: 0.3 ml (20 mg) before each meal. Dosage may be increased to 0.6 ml (40 mg) if required. Do not exceed 12 doses of 0.3 ml or 6 doses of 0.6 ml (totaling 240 mg) a day.

### 4.3. Contraindications

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

### 4.4. Special warnings and precautions for use

None stated.

### 4.5. Interactions with other medicinal products and other forms of interaction

Levothyroxine may bind to simeticone. Absorption of levothyroxine may be impaired if Tiptipot Simicol are given concurrently to infants treated for thyroid disorders.

### 4.6. Pregnancy and lactation

As simeticone is not absorbed, it is not anticipated that Tiptipot Simicol will have any adverse effects on pregnancy and lactation. However, as with all drugs, caution should be exercised in these conditions.

### 4.7. Effects on ability to drive and use machines

None stated.

### 4.8. Undesirable effects

Minor adverse effects: nausea and constipation.

Rarely, hypersensitivity reactions such as rash, pruritis, facial oedema, tongue oedema and respiratory difficulty have been reported.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

### 4.9. Overdose

No cases of overdose have been reported. Theoretically, constipation may occur. Treat with fluids and keep under observation.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

Tiptipot Simicol contain simeticone, a chemically inert gastric defoaming agent which alters the elasticity of interfaces of mucous-embedded bubbles in the gastro-intestinal tract. The gas bubbles are thus broken or coalesced and in this form, the gas is more easily eliminated through belching or passing flatus.

### 5.2. Pharmacokinetic properties

Simeticone is not absorbed from the gastrointestinal tract and does not interfere with gastric secretion or absorption of nutrients. Following oral administration, it is excreted unchanged in the faeces.

### 5.3. Preclinical safety data

None stated.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Polysorbate 80, Sorbitan Monostearate 60, Microcrystalline cellulose, Strawberry Flavour, Citric acid (anhydrous), Sodium Benzoate, Sodium Citrate, Xanthan Gum, Saccharin sodium, Purified Water.

**6.2. Incompatibilities**

None known.

**6.3. Shelf life**

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening: 2 months

**6.4. Special precautions for storage**

Store below 25°C.

**7. MARKETING AUTHORISATION HOLDER**

CTS CHEMICAL INDUSTRIES LTD

POB 385, KIRYAT-MALACHI, ISRAEL

**8. MARKETING AUTHORISATION NUMBER**

053-38-26579-00

This leaflet was revised in 03/2022 according to the MOH guidelines.