**Summary of Product Charactristics**

## 1. Name of the medicinal product:

1.1 Product Name:

TODCOL (Simethicone Oral Suspension USP)

1.2Strength:

Simethicone Emulsion USP Equivalent to Simethicone: 40 mg/ml

1.3. Pharmaceutical dosage form:

Oral suspension

Off white suspension with flavored odour.

## 2. Qualitative and quantitative composition

Composition:

Simethicone Emulsion USP

equivalent too simethicone ……40 mg

For a full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Suspension for oral use

## 4. Clinical particulars

4.1Therapeutic indications

An antiflatulant for the relief of griping pain, colic or wind due to swallowed air.

4.2Posology and method of administration

For oral administration:

Infants: (below 6 months)

0.3 – 0.7 ml four times daily. 15 mins before feeding Infants: (6 -12 months)

0.7-1.3 ml four times daily. 15 mins before feeding Children (over 1 year)

1.3 ml four times daily. 15 mins before meal Adults

5-10ml taken 20 minutes to 1 hour after meals and at bedtime or as required. Elderly

The normal adult dose is appropriate. Method of administration: oral.

Shake well before use.

4.3Contraindications:

Should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia.

4.4Special warnings and precautions for use:

The parahydroxybenzoate used in TODCOL may cause delayed hypersensitivity reactions,if symptoms persists ,seek medical advice.

This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5Interaction with other medicinal products and other forms of interaction:

Levothyroxine may also bind to simethicone which may delay or reduce the absorption of levothyroxine.

4.6Fertility, pregnancy, and lactation:

Not applicable

4.7Effects on ability to drive and use machines:

None stated.

4.8Undesirable effects:

The following CIOMS frequency rating is used, when applicable:

Very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data).

Immune system disorders:

Frequency not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

Gastrointestinal disorders: Gastrointestinal side-effects are uncommon.

Uncommon: diarrhoea or constipation

Frequency not known: Abdominal pain, Injury, poisoning and procedural complications Metabolism and nutrition disorder

4.9Overdose:

Serious symptoms are unlikely following overdosage.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk

In event of deliberate or accidental overdose, treat symptoms on appearance.

## 5. Pharmacological properties

5.1Pharmacodynamic properties:

Pharmacotherapeutic group: An antiflatulant ATC Code: A03AX13

Mechanism of action:

Physiologically the active ingredients is a chemically inert, on-systemic gastric defoaming agent that works by altering the elasticity of interfaces of mucus-embedded bubbles in the gastrointestinal tract.

The gas bubbles are thus broken down or coalesced and in this more easily eliminated through eructation or passing flatus .

5.2 Pharmacokinetic properties:

Simethicone is not absorbed from the gastrointestinal tract

5.3Preclinical safety data:

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

## 6. Pharmaceutical particulars

6.1 List of excipients

1. Dill oil BP
2. Fennel oil USP
3. Sodium methyl hydroxybenzoate BP

4. Sodium Hydroxy benzoate BP
5. Sucrose BP
6. Xanthan gum USP
7. Liquid sorbitol BP
8. Glycerin BP
9. Aspartame BP
10. Hydrophobic colloidal anhydrous silica BP
11. Polysorbate 80 BP
12. Purified water BP

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

30 months

6.4 Special precautions for storage:

Store below 30°C.protect from light. Keep medicine out of reach of children

6.5 Nature and contents of container:

15ml amber glass bottle. Such 1 bottle to be packed along with pack insert and plastic dropper

6.6 Special precautions for disposal and other handling:

No special requirements

**7. Marketing Authorization Holder**

Signature healthcare Ltd

cape business park,along Thika super highway

P.O box 66172-00800,]

Nairobi Country: Kenya

**8. Marketing Authorization Numbers**

H2025/CTD9687/20082

**9. Date of First Authorization/ Renewal of The Authorization: --**

April 2025

**10. Name and Address of Manufacturer**

Coral Laboratories Limited

Plot no 27-28, Pharmacity

Selaqui Dehradun Uttarakhand-248198.India