SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Colimix Syrup

Generic Name: Dicyclomine Hydrochloride 5mg/5ml and Simethicone 50mg/5ml Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of Syrup contains 5mg of Dicyclomine Hydrochloride and 50mg of Simethicone. Each 5ml of Syrup also contains 0.2% w/v of Methyl Hydroxybenzoate and 0.05% w/v of Propyl Hydroxybenzoate as preservatives.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

This product appears as orange-coloured syrup that is sweetly flavoured.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Colimix Syrup is indicated for removing gastrointestinal gas and relieving colic pain.

4.2. Posology and method of administration

Posology

Infant over 6 months	:	5ml before each feed. Do not exceed 4 doses in 24 hours.
Children 4-12 years	:	5 to 10ml 4 times daily.
Adults	:	10ml 3 to 4 times daily and at bedtime.

Do not exceed the stated dose.

4.3. Contraindications

Dicyclomine is not recommended for use in infants under the age of six months.

4.4. **Special warnings and precautions for use**

Dicyclomine is an anticholinergic and the usual precautions should be observed in patients with glaucoma, prostatic enlargement, urinary retention, tachycardia, cardiac insufficiency, paralytic ileus, ulcerative colitis or pyloric stenosis. May aggravate oesophageal reflux. The safety of this product in pregnancy has not been fully established and should be carefully assessed by the physician before use.

4.5. **Interaction with other medicinal products and other forms of interaction**

N/A.

4.6. **Pregnancy and lactation**

N/A.

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

N/A.

4.8. **Undesirable effects**

Simethicone is physiologically inert, nonabsorbable substance and does not cause any side effect. Dicyclomine Hydrochloride, being poorly absorbed, possesses less anticholinergic side effects compared with atropine. The following effects may be observed with high doses: dry mouth, urinary hesitancy and retention, blurred vision, tachycardia, palpitations, flushing and dryness of the skin, constipation, mydriasis, increase ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, suppression of lactation, nausea, vomiting, mental confusion and/or excitement, especially in elderly persons and decreases sweating.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents

4.9. **Overdose**

N/A.

5. PHARMACOLOGICAL PROPERTIES

5.1. **Pharmacodynamic Properties**

Pharmacotherapeutic group: Dicycloverine, ATC Code: A03AA07

5.2. **Pharmacokinetic Properties**

N/A.

5.3. **Preclinical safety data**

N/A.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Syrup
Colloidal Silicon Dioxide
Tragacanth
Glycerin
Ethyl
Maltol
Methyl
Hydroxybenzoate
Propyl
Hydroxybenzoate
Chloroform Spirit
Saccharin Sodium
Sunset Yellow
Colour Banana
Flavour Butter
Flavour
Orangina Base Flavour

Purified Water

6.2 Incompatibilities

N/A.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 **Nature and contents of**

container 60ml in Amber PET Bottle. 90ml in Amber PET Bottle.

6.6 Special precautions for disposal and other handling

None.

7. Manufacturer

Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.,
1-5, Cheng Industrial Estate, 75250 Melaka, Malaysia.

8.Marketing authorization number

H95/234

9.Date Of First / Renewal Of The Registration

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10. Date of Revision of Text

09/08/2024