

**PATIENT LEAFLET IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

## Simicol tablets

### 125 mg

Each tablet contains: Simethicone 125 mg

For inactive ingredients and allergens in the preparation, see the section "Important information about some ingredients of the medicine" and section 6.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information.

In case the symptoms of your illness worsen or do not improve, refer to the doctor.

Simicol tablets is usually not intended for infants and children under 12 years of age. Under this age it is recommended to use Tiptipol Simicol.

### 1. What is the medicine intended for?

The medicine is intended for relieving bloating and flatulence in the digestive system.

**Therapeutic class:** anti-flatulents

### 2. Before using the medicine:

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (see section 6).

### 3. Drug interactions

**If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist.** Especially if you are taking:

- Levothyroxine for treatment of thyroid disorders. Simicol tablets may reduce the amount of absorbed levothyroxine and diminish its effect.

### 4. Use of the medicine and food

The medicine should be taken after a meal.

### 5. Pregnancy, breastfeeding and fertility

Consult a doctor or a pharmacist before starting the treatment if you are pregnant, might be pregnant, planning to become pregnant, or are breastfeeding. Do not use this preparation during pregnancy unless the doctor tells you to.

### 6. Important information about some ingredients of the medicine

The preparation contains a mixture of sugars. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

### 7. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

**For adults and children above 12 years of age:** 1-2 tablets after a meal or at bedtime as necessary.

Do not take more than 4 tablets in 24 hours.

**Do not exceed the recommended dose.**

This medicine is usually not intended for infants and children under 12 years of age, due to the form of administration/the available dosage through this form of administration. Under this age it is recommended to use Tiptipol Simicol.

Do not chew! The medicine should be swallowed with water.

The tablet may be halved.

**If you took an overdose** or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

**If you have forgotten to take this medicine at the required time**, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

### 8. Side effects:

As with any medicine, using Simicol tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Possible side effects are nausea, constipation or an allergic reaction, such as skin rash or itch, swelling of the face or tongue or breathing difficulties.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

### 9. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp.) appearing on the package. The expiry date refers to the last day of that month.

**Storage:** Store at a temperature lower than 25°C.

### 10. Additional information:

**In addition to the active ingredient, the medicine also contains:**

Tribasic calcium phosphate, Dextrates, Microcrystalline cellulose, Sodium starch glycolate, Magnesium stearate, Colloidal silicon dioxide, FD&C blue no.1 lake

**What does the medicine look like and what are the contents of the package:**

Blister pack of 10 tablets. Each pack contains 20 or 30 tablets. The tablets are round and light-blue.

**Manufacturer/license holder and address:** CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi. This leaflet was revised in 09/2021 in accordance with the Ministry of Health guidelines.

**Registration number of the medicine in the national drug registry of the Ministry of Health:** 1487933834



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