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

This medicine is dispensed without a doctor's prescription

Tiptipot Simicol

Oral drops

The active ingredient and its concentration:
Simethicone 20 mg/0.3 ml (66.67 mg/1 ml)
Inactive ingredients and allergens in the preparation – see the subsection "Important information about some of the 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. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

1. What is the medicine intended for?

The medicine is intended for the relief of abdominal pain in infants and young children caused by the accumulation of gas.

Therapeutic class: medicines for the relief of gastrointestinal gas.

2. Before using the medicine:

☒ Do not use this medicine if:

- There is a known sensitivity (allergy) to the active ingredient or to any of the other ingredients this medicine contains (see section 6).

❗ Drug interactions:

If the child is taking or has recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if the child is taking:

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

❗ Pregnancy, breastfeeding and fertility:

Tiptipot Simicol is intended especially for children. If you are an adult woman using the medicine, consult a doctor or pharmacist before starting treatment if you are pregnant, may be pregnant, are planning to become pregnant or are breastfeeding.

Do not use the preparation during pregnancy unless the doctor tells you to.

❗ Important information about some of the ingredients of the medicine:

The medicine contains 1.2 mg of sodium benzoate per 0.6 ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in infants up to 4 weeks of age.

The medicine contains less than 23 mg of sodium per dose and is therefore considered sodium-free.

3. 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:
0.3 ml (20 mg) before each meal. The dosage can be increased to 0.6 ml (40 mg) if necessary.

Do not exceed 12 doses of 0.3 ml or 6 doses of 0.6 ml (240 mg in total) per day.

During the period of treatment with the medicine, it is advisable to consult a doctor for the purpose of diagnosing the cause of gas accumulation.

Do not exceed the recommended dose.

Method of use:

1. Shake well before use.
2. Fill the enclosed syringe to the desired amount and drip into the mouth.
3. After use, separate the parts of the syringe and rinse the two parts of the syringe thoroughly with lukewarm water.

With liquid medicines, use the syringe or dropper intended for measuring the correct amount of medicine. If a measuring device is not included in the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size and it is likely you will not receive the correct amount of medicine.

If the child has taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to give the medicine at the required time, do not give a double dose. Administer the next dose at the regular time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> 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.

4. Side effects:

As with any medicine, using Tiptipot Simicol may cause side effects in some users. Do not be alarmed when reading the list of side effects. The child may not suffer from any of them.

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

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.

<u>Reporting side effects:</u>

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), which will direct you to the online form for reporting side effects, or by clicking on the following link:
https://sideeffects.health.gov.il/

5. 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.

Store at a temperature below 25°C.

Once the bottle has been opened, Tiptipot Simicol may be used for 2 months.

6. Additional information:

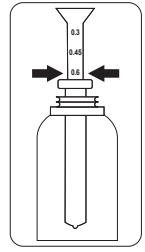
In addition to the active ingredient, the medicine also contains:
Polysorbate 80, Sorbitan Monostearate 60, Microcrystalline cellulose, Strawberry Flavour, Citric acid (anhydrous), Sodium Benzoate, Sodium Citrate, Xanthan Gum, Saccharin sodium, Purified Water.

What does the medicine look like and what are the contents of the package:
A glass bottle containing 30 ml of a white and viscous caramel-flavored emulsion.

Name of manufacturer/marketing authorization holder and address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.

This leaflet was revised in 03/2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 533826579



LFL 639 03/22