This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved
PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed without a doctor's prescription

ACAMOLi® 125mg/5ml

Strawberry Flavoured Syrup – Sugarless
Fruit Flavoured Syrup – Sugarless
Raspberry Flavoured Syrup – Sugarless

Composition
Each 5 ml contains: Paracetamol 125 mg
For the list of inactive ingredients in the preparation, see section 6 – "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is dispensed without a doctor's prescription. The medicine is intended for children, but in children below the age of 3 years, consult a doctor before use. Take the medicine properly. Consult a pharmacist if you need further information. Refer to a doctor if the fever persists for more than 3 days or if the symptoms do not pass within 5 days despite use of the medicine.

The medicine can also be taken by adults, and therefore, the information in this leaflet is also intended for adults taking this medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?
The medicine is intended to relieve pain and reduce fever.

Therapeutic group:
Analgesic and antipyretic.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- Do not use this medicine if you have a known sensitivity to paracetamol or to any of the other ingredients of the medicine (see section 6).

Special warnings regarding use of the medicine:
- If you have developed in the past skin side effects as a result of taking preparations containing paracetamol, do not take preparations containing paracetamol, so that severe skin effects will not recur.
- If you or your child are sensitive to any food or medicine, inform the doctor before taking the medicine.
- The preparation contains paracetamol which may cause liver damage when:
  - Given at a dosage higher than recommended or for a prolonged period.
  - Consuming alcoholic beverages during the course of treatment.
  - Taking additional medicines which affect liver function.
- Do not use this medicine often without consulting a doctor.
- Do not take additional antipyretics and analgesics or cold medicines without consulting a doctor or pharmacist, to prevent paracetamol overdose/poisoning.
- Avoid taking a high dosage of this medicine (even if within the recommended dosage range) when fasting.

! Consult a doctor before commencing treatment if you or your child are suffering, or have suffered in the past, from:
- Impaired liver function
- Impaired kidney function
- Alcoholism
- Jaundice

! If you or your child are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements and vitamins, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:
- Phenytoin, carbamazepine (for treatment of epilepsy)
- Anticoagulants
- Medicines which accelerate production of enzymes in the liver (e.g., barbiturates)
- Non-steroidal anti-inflammatory preparations
- Metoclopramide or domperidone (to treat nausea, vomiting and other digestive problems)
- Antibiotics (e.g., rifampicin or chloramphenicol)
- Probenecid (to treat gout)
- Cholestyramine (to reduce excess of blood lipids)
- Do not take this medicine together with other paracetamol-containing preparations

! Use of paracetamol and alcohol consumption
During the course of treatment with paracetamol, do not consume alcohol due to increased risk of liver damage.

! Pregnancy and breastfeeding
If you are pregnant or breastfeeding, consult a doctor before starting use of this medicine.

! Use in children
Consult the doctor when using this medicine in children below the age of 3 years.
Parents must report to the attending doctor of any side effects as well as any additional medicine being given to the child.

! Important information about some of the ingredients of the medicine
- The medicine contains methylparaben and propylparaben which may cause allergic reactions (delayed reactions are possible).
- The medicine contains xylitol sweetener in the amount of 1.25 g in every 5 ml syrup. There may be a mild laxative effect. The caloric value is 2.4 kcal per 1 g xylitol.
- The medicine contains sodium.

3. HOW SHOULD YOU USE THE MEDICINE?
Check with the doctor or pharmacist if you are uncertain as to how to use this medicine.

The usual dosage unless otherwise instructed by the doctor:
Children
Find the suitable dosage in the following tables.

If you know the child's weight – give the dosage as shown in the weight table indicating dosage according to weight.

Only if the child's weight is not known – the dosage will be determined according to age, as shown in the age table indicating dosage according to the child's age.

Weight Table

Child's weight	Dose in ml	Number of maximum daily doses
3 kg	1.8	Up to 5 times per day
4 kg	2.4	Up to 5 times per day
5 kg	3.0	Up to 5 times per day
6 kg	3.6	Up to 5 times per day
7 kg	4.2	Up to 5 times per day
8 kg	4.8	Up to 5 times per day
9 kg	5.4	Up to 5 times per day
10 kg	6.0	Up to 5 times per day
11 kg	6.6	Up to 5 times per day
12 kg	7.2	Up to 5 times per day
13 kg	7.8	Up to 5 times per day
14 kg	8.4	Up to 5 times per day
15 kg	9.0	Up to 5 times per day
16 kg	9.6	Up to 5 times per day
17 kg	10.2	Up to 5 times per day
18 kg	10.8	Up to 5 times per day
19 kg	11.4	Up to 5 times per day
20 kg	12.0	Up to 5 times per day

Age Table
Children of identical ages can be of significantly different weights. Therefore, make an effort to find out the child's weight and to determine the dosage according to the weight table. Only if it is not possible to find out the child's weight can the dosage be determined according to this table.

Child's age	Dose in ml	Number of maximum daily doses
0-3 months	1.6	Up to 5 times per day
4-11 months	3.2	Up to 5 times per day
12-23 months	4.8	Up to 5 times per day
2-3 years	6.4	Up to 5 times per day
4-5 years	9.6	Up to 5 times per day
6-8 years	12.8	Up to 5 times per day
9-10 years	16.0	Up to 5 times per day
11 years	19.2	Up to 5 times per day

Do not exceed the recommended dose or the number of maximum daily doses.
Take/administer the doses at intervals of not less than 4 hours.

Children above the age of 12 years:
20 ml every 4-5 hours, as needed. Do not exceed the recommended dose.

Adults:
20 ml every 4-5 hours, as needed. Do not exceed 4 grams of paracetamol (present in 160 ml syrup) within 24 hours.

Refer to a doctor if the fever persists for more than 3 days or if the symptoms do not pass within 5 days despite use of the medicine.

Directions for use
- Use the provided syringe for dosage accuracy. Each line on the syringe measures 0.1 ml.
- Insert the syringe into the special opening in the bottleneck. While holding the syringe in place, turn the bottle upside down and gently pull the plunger of the syringe downward, until the required marking (the amount of medicine in ml). After filling, turn the bottle upright and gently release the syringe.
- Place the syringe into the child's mouth, towards the cheek, and empty its contents slowly.
- After use and before inserting the syringe into the bottle again, separate the parts of the syringe and wash with lukewarm water and soap.

If you or your child took an overdose or if a child accidentally swallowed this medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Even if you feel well despite taking an overdose, immediate treatment is essential, **due to the risk of developing severe liver damage.** Overdose may cause the following symptoms: nausea, vomiting, diarrhoea, loss of appetite, stomach pains, flatulence, pain or tenderness in the upper abdomen. They may not reflect the severity of the liver damage.

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

4. SIDE EFFECTS
As with any medicine, use of Acamoli® 125 mg/5 ml may cause side effects, such as dizziness, in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects
Discontinue treatment and refer to a doctor immediately:
- If allergic reactions occur, such as rash and itching, swelling of the face, lips, tongue, throat, that can cause difficulty breathing or swallowing, swelling of the limbs.
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases, whose signs can be: redness, rash, blisters, widespread skin damage.
  Severe skin side effects may appear even if you have previously taken preparations containing the active ingredient paracetamol and did not suffer from side effects.
  If skin side effects appear, discontinue treatment and refer to a doctor immediately.
- If signs of changes in the blood system occur, such as: bleeding, bruises, development of inflammations more easily.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects.

5. HOW SHOULD THE MEDICINE BE STORED?
- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Do not store in the refrigerator.
- Can be used for up to 6 months from first opening the bottle but not later than the expiry date that appears on the package.

6. FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains:
Water, xylitol, povidone, glycerin, propylene glycol, acesulfame potassium, methylparaben, ammonium glycyrrhizinate, vanilla flavour, propylparaben, colour red FDC No. 40, sodium hydroxide.

Acamoli® 125 mg/5 ml Strawberry Flavour also contains: Strawberry flavour

Acamoli® 125 mg/5 ml Fruit Flavour also contains: Tutti frutti flavour, colour blue FDC No. 2

Acamoli® 125 mg/5 ml Raspberry Flavour also contains: Passion fruit flavour, colour blue FDC No. 2

What does the medicine look like and what are the contents of the package?
Each package contains a bottle of syrup and a syringe for dosage accuracy. Volume per package: 60 ml (general sale), 100 ml, 150 ml. Not all package sizes may be marketed.
Acamoli® 125 mg/5 ml Strawberry Flavour: a red to brown-red, transparent syrup.
Acamoli® 125 mg/5 ml Fruit Flavour: a pink-red to brown-red, transparent syrup.
Acamoli® 125 mg/5 ml Raspberry Flavour: a pink-red to brown-red, transparent syrup.

Manufacturer and license holder:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach-Tikva.

This leaflet was checked and approved by the Ministry of Health in September 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Acamoli® 125 mg/5 ml Strawberry Flavour: 139.02.31737.00
Acamoli® 125 mg/5 ml Fruit Flavour: 139.01.31739.00
Acamoli® 125 mg/5 ml Raspberry Flavour: 138.99.31738.00

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