

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Acamoli® Forte

50 mg/1 ml Strawberry Flavour Syrup

Acamoli® Forte

50 mg/1 ml Tutti-Frutti Flavour Syrup

Composition

Each 1 ml contains:
Paracetamol 50 mg.

For information regarding inactive ingredients and allergens, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Take the product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if the fever persists for more than 3 days or if the symptoms do not resolve within 5 days.

The preparation is given from the age of 0 and weight of at least 3kg. For babies who weigh less than 3 kg, consult the doctor.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to relieve pain and reduce fever.

Therapeutic class:

Analgesic and antipyretic.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

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

Special warnings regarding the use of the medicine:

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

While using this medicine, tell the doctor immediately if:
You have severe diseases, including severe renal impairment or sepsis (when bacteria and their toxins are present in the blood, leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (an abnormality of the blood and body fluids) has been reported in patients in these situations when paracetamol is used at regular dosages for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with rapid deep breathing, drowsiness, feeling nausea and vomiting.

The doctor/pharmacist may advise you to give the medicine at a lower dosage or less frequently if your child:

- Is underweight for his age
- Suffers from acute or chronic eating problems (such as malnutrition, fasting, dietary restrictions, eating disorders, starvation).
- Suffers from sepsis, cachexia (severe loss of weight and muscle mass due to an illness) or a chronic illness (such as cystic fibrosis, liver disease, HIV, muscular dystrophy)

In these cases, follow the instructions of the doctor/pharmacist

When used in adults, the doctor/pharmacist may advise you to take the medicine at a lower dosage or less frequently if:

- You are elderly
- You weigh less than 50 kilograms
- You have liver or kidney problems
- You are taking other medicines
- You consume excessive amounts of alcohol
- You suffer from acute or chronic eating problems (such as malnutrition, fasting, dietary restrictions, eating disorders, starvation)
- You have sepsis, cachexia (severe loss of weight and muscle mass due to an illness) or a chronic illness (such as cystic fibrosis, liver disease, HIV, muscular dystrophy)

In these cases, follow the instructions of the doctor/pharmacist

Consult a doctor before starting treatment if you or your child suffer or have suffered in the past from:

- Liver dysfunction
- Impaired kidney function
- Alcoholism
- Jaundice

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines, nutritional supplements and vitamins, tell the doctor or the 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, barbiturates (for treatment of epilepsy)
- Medicines against blood clotting (such as warfarin)
- Antidepressants (such as tricyclic antidepressants)
- Medicines that stimulate the production of enzymes in the liver (such as barbiturates)
- Non-steroidal anti-inflammatory preparations
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Antibiotics (such as rifampicin or chloramphenicol)
- Probenecid (for treatment of gout)
- Cholestyramine (for reducing excess blood lipids)
- Do not take this medicine together with other preparations that contain paracetamol
- Using oral contraceptives may decrease the effectiveness of this medicine in reducing pain or fever
- Flucloxacillin (an antibiotic), due to a serious risk of disorders in the blood and body fluids (this

disorder is called metabolic acidosis), this disorder requires urgent treatment (see section 2 "Before using the medicine")

Use of paracetamol and alcohol consumption

During treatment with paracetamol, do not consume alcohol due to increased risk of liver damage.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not take the medicine unless the doctor has advised you to. If necessary, take the lowest dose that is effective for relieving your pain and/or reducing your fever, for the shortest duration possible. Consult the doctor if there is no reduction in pain or in fever or if you need to take the medicine more often.

Use in children

Parents must report to the treating doctor all side effects and any additional medicine given to the child.

Important information about some of the ingredients of the medicine

- The medicine contains the sweetener xylitol in an amount of 1.5 grams in every 5 ml syrup. There may be a mild laxative effect. The caloric value is 2.4 kcal per 1 gram xylitol.
- The medicine contains colour red FDC No. 40, which may cause an allergic reaction.
- The medicine contains sodium in an amount of 5.86 mg in every 5 ml syrup. The medicine contains less than 1 mmol (23 mg) sodium in every 5 ml syrup and is therefore considered sodium-free.
- This medicine contains 625 mg propylene glycol in every 5 ml syrup. Consult the doctor or pharmacist before starting treatment:
 - If your child is under 5 years of age, particularly if your child is being treated with other medicines containing propylene glycol or alcohol.
 - Do not take this medicine if you suffer from liver or kidney disease. The doctor may ask you to undergo additional tests while taking this medicine.
 - Do not take the medicine if you are pregnant or breastfeeding, unless recommended by the doctor. The doctor may ask you to undergo additional tests while taking this medicine.

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.

Standard dosage when no other instruction from the doctor is given:

Children

The preparation is given from the age of 0 and weight of at least 3 kg.

For babies who weigh less than 3 kg, consult the doctor.

Find the suitable dosage in the following tables.

If you know the child's weight - the dosage should be given 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 for Acamoli Forte 50 mg/1 ml:

Child's weight	Dose in ml	Maximum number of doses per 24 hours
3 kg	0.9	Up to 5 times a day
4 kg	1.2	Up to 5 times a day
5 kg	1.5	Up to 5 times a day
6 kg	1.8	Up to 5 times a day
7 kg	2.1	Up to 5 times a day
8 kg	2.4	Up to 5 times a day
9 kg	2.7	Up to 5 times a day
10 kg	3.0	Up to 5 times a day
11 kg	3.3	Up to 5 times a day
12 kg	3.6	Up to 5 times a day
13 kg	3.9	Up to 5 times a day
14 kg	4.2	Up to 5 times a day
15 kg	4.5	Up to 5 times a day
16 kg	4.8	Up to 5 times a day
17 kg	5.1	Up to 5 times a day
18 kg	5.4	Up to 5 times a day
19 kg	5.7	Up to 5 times a day
20 kg	6	Up to 5 times a day
21 kg	6.3	Up to 5 times a day
22 kg	6.6	Up to 5 times a day
23 kg	6.9	Up to 5 times a day
24 kg	7.2	Up to 5 times a day
25 kg	7.5	Up to 5 times a day
26 kg	7.8	Up to 5 times a day
27 kg	8.1	Up to 5 times a day
28 kg	8.4	Up to 5 times a day
29 kg	8.7	Up to 5 times a day
30 kg	9	Up to 5 times a day

Age table for Acamoli Forte 50 mg/1 ml:

Children of identical ages can be of significantly different weights. Therefore, an effort must be made to find out the child's weight and 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	Maximum number of doses per 24 hours
0-3 months in babies weighing 3 kg or more	0.8	Up to 5 times a day
4-11 months	1.6	Up to 5 times a day
12-23 months	2.4	Up to 5 times a day
2-3 years	3.2	Up to 5 times a day
4-5 years	4.8	Up to 5 times a day
6-8 years	6.4	Up to 5 times a day
9-10 years	8	Up to 5 times a day
11 years	9.6	Up to 5 times a day

For babies who weigh less than 3 kg, consult the doctor

Do not exceed the recommended dose or the maximum number of daily doses.
Take/administer the doses at intervals of at least 4 hours.
Children 12 years of age and above:
10 ml every 4-5 hours, as needed. Do not exceed the recommended dose.
Adults:
10 ml every 4-5 hours, as needed. Do not exceed 4 grams of paracetamol (found in 80 ml syrup) within 24 hours. Use in the elderly: the doctor may advise taking a lower dosage.

Refer to the doctor if the fever persists for more than 3 days or if the symptoms do not resolve

within 5 days despite use of the medicine.

Method of use

- Use the enclosed syringe for dosage accuracy. Each hash mark (line) on the syringe measures 0.1 ml.
- Insert the syringe into the special opening in the neck of the bottle. While the syringe is held in place, turn the bottle upside down and gently pull the plunger of the syringe down to the desired mark (the amount of medicine in ml). After filling, turn the bottle back over and gently release the syringe.
- Insert the syringe into the child's mouth, towards the cheek, and empty its content 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, refer to a doctor or a hospital emergency room immediately 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.

Overdosing may cause the following symptoms: pale skin, nausea, vomiting, diarrhea, feeling of discomfort, loss of appetite, abdominal pain, swelling, increased sweating, pain or tenderness in the upper abdomen, and the symptoms may not reflect the severity of liver damage.

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 use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Acamoli Forte 50 mg/1 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 experience any of them.

Severe side effects

You should stop the treatment and contact the doctor immediately:

- If acute allergic reactions appear such as rash and itching, swelling of the face, lips, tongue, throat, or neck which can cause breathing or swallowing difficulties, swelling of the extremities. Unexplained wheezing-rhonchi.
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases whose signs can be: redness, rash, blisters, skin peeling and lesions, widespread skin damage. Acute skin side effects may appear even if you have previously taken preparations containing the active ingredient paracetamol without suffering from side effects. If skin side effects appear, discontinue treatment and refer to a doctor immediately.
- Unusual tiredness, unexpected bruising or bleeding, tendency to have more infections (such as the common cold) than usual. These are very rare effects in people taking paracetamol.
- A serious condition called metabolic acidosis, which can make the blood more acidic, in patients with a severe disease using this medicine (see section 2 "Before using the medicine"). The frequency of this side effect is unknown (frequency cannot be estimated from the available data).

Long-term use: using medicines containing paracetamol every day for a long time (several months or more) may cause certain side effects, including damage to the liver and kidneys. When taking paracetamol in the accepted dosage for short time periods, these effects did not occur, but there may be an effect on liver function tests.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not indicated in the leaflet, consult with the doctor.

Reporting side effects

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. Date) appearing on the package. The expiry date refers to the last day of that month.
- **Store below 25°C. Do not store in the refrigerator.**
- After opening the bottle for the first time, the medicine can be used up to the expiry date.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, Acamoli Forte 50 mg/1 ml Strawberry Flavour also contains:

Water, xylitol, propylene glycol, glycerin, povidone, sodium citrate dihydrate, acesulfame potassium, citric acid monohydrate, flavour strawberry, ammonium glycyrrhizinate, flavour vanilla, colour red FDC No. 40

In addition to the active ingredient, Acamoli Forte 50 mg/1 ml Tutti-Frutti Flavour also contains:

Water, xylitol, propylene glycol, glycerin, povidone, sodium citrate dihydrate, acesulfame potassium, citric acid monohydrate, flavour tutti-frutti, ammonium glycyrrhizinate, flavour vanilla, colour red FDC No. 40, 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.

Acamoli Forte 50 mg/1 ml Strawberry Flavour: a transparent red to brown-red syrup.

Acamoli Forte 50 mg/1 ml Tutti-Frutti Flavour: a transparent pink-red to brown-red syrup.

The package size is 50 ml or 100 ml. Not all package sizes may be marketed.

Manufacturer:

Vitamed Pharmaceutical Industries Ltd., P. O. Box 114, Binyamina 3055002, Israhel.

License holder: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

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Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Acamoli Forte 50 mg/1 ml Strawberry Flavour Syrup: 140.18.31762

Acamoli Forte 50 mg/1 ml Tutti-Frutti Flavour Syrup: 140.17.31761

You may contact the license holder for a printed leaflet in English at:

Tevacare@med-trix.com or by telephone: 1-800-805-005

