#### Paracetamol/Caffeine 500 mg/50 mg tablets

# What is Paracetamol/Caffeine Teva 500 mg/50 mg and what is it used for?

Drug group: Paracetamol/Coffeine Teva works as a pain reliever and fever reducer.

## Uses:

- For fever and pain associated with the flu and cold.
- For fever and pain after vaccination.
- For headache.
- For toothache.
- For back pain and muscle pain.
- For menstrual pain.
- For nerve pain.

## When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine if you have:

Liver or kidney function disorders, Moderate to severe kidney insufficiency (poor kidney function), Mild to severe liver insufficiency (poor liver function), Gilbert's syndrome (liver disease), Glucose-6-phosphate dehydrogenase deficiency (lack of glucose-6-phosphate dehydrogenase (enzyme)), Hemolytic anemia (anemia caused by the destruction of red blood cells), Dehydration, Chronic malnutrition, Asthmatic patients who are sensitive to aspirin (= acetylsalicylic acid)

An infection that worsens and is accompanied by deep, rapid, and difficult breathing, nausea, and vomiting after taking paracetamol. Contact a doctor immediately if you experience these symptoms.

In chronic alcoholism, the daily dosage should not exceed 2 grams of paracetamol (this corresponds to 4 tablets of Paracetamol/Coffeine Teva 500 mg/50 mg).

## How to use this medication?

At least 4 hours must have passed before taking the next dose. Use this medication again only if the symptoms recur (fever and pain). If the pain lasts longer than 5 days or the fever lasts longer than 3 days, or worsens, or if other symptoms occur, treatment should be stopped and a doctor should be consulted.

Adults: 1-2 tablets at a time, maximum 6 tablets per day (=24 hours).

Children: Age Dosage Maximum daily dose

- 6-9 years (22-30 kg) ½ tablet 4-6 times a day 2-3 tablets
- 9-12 years (30-40 kg) 1 tablet 3-4 times a day 3-4 tablets
- 12-15 years (40-55 kg) 1 tablet 4-6 times a day 4-6 tablets

For children who belong to the lower limit of a certain category in terms of age or weight, the lower number of times per day should be dosed. For example, a 6-year-old child may only take half a tablet 4 times a day.

Reduced functioning of the kidneys

In case of insufficient functioning of the kidneys (renal insufficiency), the dose should be reduced.

## Maximum daily dose (exceptions)

The effective daily dose should not exceed 60 mg/kg/day (up to 2 grams per day) in the following situations:

adults weighing less than 50 kg, reduced functioning of your liver (hepatic insufficiency), Gilbert's syndrome; a liver disease. This disease is hereditary. Hereditary often means that the disease runs in your family dehydration, chronic malnutrition, chronic alcoholism.

If you notice that this medicine is too strong or not effective enough, consult your doctor or pharmacist.

## Method of use

The tablets are best taken with a large amount of water (= ½ glass). You should not use the tablets for longer than 14 days without consulting a doctor.

## Have you used too much of this medication?

If you have taken too much of this medicine, contact your doctor or pharmacist immediately. Taking a higher dose than indicated may cause nausea, vomiting, and loss of appetite. Taking several times the maximum daily dose at once can cause very serious liver damage. Unconsciousness usually does not occur, but you should seek immediate medical help. Delayed action can result in irreparable liver damage.

#### Did you forget to use this medicine?

This leaflet only contains a summary of the information on the medicine. The content of this leaflet should not be considered complete. It should not be used in place of a call or visit to a medical, health or other competent professional, who should be consulted before adopting any of the suggestions on this leaflet. No rights can be derived from the information provided in this instruction leaflet. Approved by pharmacist: M.H.H Janssen on 30-1-2023

Do not take a double dose of this medicine to make up for a missed dose. Simply continue with the indicated dosing schedule.

#### If you stop using this medicine

The use of this medicine can be stopped suddenly without consequences. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### Possible side effects

Like all medicines, this medicine can have side effects, although not everybody gets them. The following side effects have been reported:

Rarely (1 in 10,000 to 1 in 1,000 users): Various blood disorders, including agranulocytosis (too few white blood cells, making you more prone to infections), thrombocytopenia (too few platelets in your blood, which help to form clots), thrombotic thrombocytopenic purpura (clotting in the blood vessels), leukopenia (too few white blood cells), and hemolytic anemia (anemia caused by the destruction of red blood cells).

- Allergies (excluding swelling of the face, tongue, and throat, which can cause difficulty breathing (angioedema)).
- Abnormal liver function, liver failure, liver necrosis (liver damage), and jaundice.
- Itching (pruritus), rash, sweating, red or purple spots on the skin (purpura), and hives (urticaria).
- Overdose and poisoning.
- Depression, confusion, and hallucinations.
- Tremors and headaches.
- Blurred vision.
- Fluid retention (edema).
- Bleeding, stomach pain, diarrhea, nausea, vomiting.
- Dizziness, fever, and drowsiness.

Very rarely (less than 1 in 10,000 users): Pancytopenia (reduction in the number of blood cells).

Hypersensitivity reactions requiring discontinuation of treatment, including angioedema, Quincke's edema, difficulty breathing, sweating, nausea, hypotension, shock, and anaphylaxis.

Breathlessness caused by spasm of the airway muscles (bronchospasm) in individuals who are sensitive to aspirin and other NSAIDs (group of pain relievers with anti-inflammatory and antipyretic effects).

- Liver poisoning.
- Skin rash (exanthem).
- Hypoglycemia (low blood sugar).
- Dark urine (sterile pyuria) and kidney reactions.
- Very rare cases of severe skin reactions have been reported.

## How to store this medicine?

There are no special storage conditions for this medicine.