

PACKAGE LEAFLET: Information for the patient

TEMAGIN PARACETAMOL PLUS

Tablets – 350 mg / 50 mg

(Paracetamol / Caffeine)

For use in adults and adolescents from 12 years old.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine as prescribed in this leaflet or as directed by a doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- If you need further information or advice, ask your pharmacist.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If after 3 days you do not get better or get worse, consult a doctor.

What is in this leaflet:

1. What is Temagin Paracetamol plus and what it is used for
2. What you should know before you take Temagin Paracetamol plus
3. How to take Temagin Paracetamol plus
4. Possible side effects
5. How to store Temagin Paracetamol plus
6. Other information

1. WHAT IS TEMAGIN PARACETAMOL PLUS IS AND WHAT IT IS USED FOR

Temagin Paracetamol plus is a combination of paracetamol, which relieves pain and lowers temperature (analgesic and antipyretic drug), and caffeine.

Temagin Paracetamol plus is indicated for the symptomatic treatment of mild to moderate pain (such as, headache, toothache, menstrual pain).

If after 3 days you are not getting well, or get worse, or have high fever, consult your doctor.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE TEMAGIN PARACETAMOL PLUS

Do not take Temagin Paracetamol plus:

- if you are hypersensitive to paracetamol, caffeine or any of the excipients listed in section 6
- if you are a child under 12 years old.

Take special care when taking Temagin Paracetamol plus

Talk to your doctor or pharmacist before you start taking Temagin Paracetamol plus.

Take Temagin Paracetamol plus only after talking to your doctor in the following cases:

- you are a chronic alcohol abuser;
- you suffer from impaired liver function (inflammation of the liver, Gilbert's syndrome);
- in hyperthyroidism;
- in arrhythmias;
- in anxiety disorders.

To prevent the risk of overdose, it should be ensured that simultaneously used drugs do not contain paracetamol.

In the event of protracted use of analgesics at high doses and not in line with the intended use, headaches may occur that must not be treated with increased doses of the medicinal product.

Quite generally, the habitual intake of analgesics, particularly when different analgesic drugs are combined, can cause permanent renal damage with the risk of renal failure (analgesic nephropathy).

With abrupt withdrawal after prolonged high-dose, incorrect use of analgesics, headaches, fatigue, muscle pain, nervousness and autonomic symptoms may occur. The symptoms disappear within a few days after discontinuation. Until then, the re-use of analgesics should be avoided and the re-taking should not take place without medical advice.

You should not take Temagin Paracetamol plus in higher doses or for longer than recommended without the advice of your doctor or dentist.

During treatment with Temagin Paracetamol plus , tell your doctor straight away if:

You have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate 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 (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Children

The safety of Temagin Paracetamol plus has not been established in children under the age of 12.

Taking Temagin Paracetamol plus with other medicines

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines.

Paracetamol

The following interactions are possible with:

- anti-gout drugs, such as probenecid: with concomitant administration of probenecid, the dose of Temagin Paracetamol plus should be reduced because the metabolism of paracetamol may be prolonged;
- sedative drugs such as phenobarbital, antiepileptics such as phenytoin, carbamazepine, antituberculosis (rifampicin), other drugs that can damage the liver: concomitant use with Temagin Paracetamol plus may damage the liver;
- antiemetic drugs (metoclopramide and domperidone): these drugs may accelerate the absorption and onset of action of Temagin Paracetamol plus;
- drugs to lower high blood fats level (cholestyramine): these drugs may reduce the absorption and consequently the effect of Temagin Paracetamol plus;

- medicines used in HIV infection (zidovudine): the tendency to decrease white blood cells (neutropenia) is enhanced; Temagin Paracetamol plus can be used concomitantly with zidovudine only with a doctor's recommendation;
- medicines that delay gastric emptying can lead to a delayed onset of effect;
- warfarin or other coumarins, (blood thinning drugs) – if you take warfarin you can take occasional doses of this medicine, but talk to your doctor first before you take it on a regular basis;
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment.

Effects of Temagin Paracetamol plus on laboratory values

The uric acid and glucose determination can be affected.

Caffeine

The following interactions are possible with:

- sedative drugs, such as barbiturates, antihistamines (anti - allergic drugs), etc.: the hypnotic effect is reduced;
- drugs that increase heart rate, such as sympathomimetics (cardiovascular agents), thyroxine (thyroid agent), etc.: the effect that increases heart rate is enhanced;
- paracetamol and some nonsteroidal anti-inflammatory drugs (some analgesics): the analgesic effect increases;
- theophylline (drug for the treatment of lung diseases): caffeine reduces the excretion of theophylline;
- ephedrine-type substances: their potential to cause addiction increases;
- oral contraceptives, cimetidine (drug for the treatment of gastric ulcer) and disulfiram (drug for the specific treatment of alcohol dependence): the metabolism of caffeine in the liver is reduced;
- barbiturates (sedative drugs) and smoking: the metabolism of caffeine in the liver is accelerated;
- gyrase inhibitors of the quinolone carboxylic acid-type (drugs for the treatment of infections): these drugs can delay the elimination of caffeine and its metabolite paraxanthine;

- lithium, this product is not recommended if you are taking lithium.

Taking Temagin Paracetamol plus with alcohol

You should not drink alcohol while taking Temagin Paracetamol plus.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or if you suspect you are pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy

During pregnancy, Temagin Paracetamol plus can be taken only after a very careful evaluation of the benefit / risk ratio.

During pregnancy you should not take Temagin Paracetamol plus for a long time, in high doses or in combination with other drugs because the safety of use in these cases has not been determined.

Breastfeeding

Paracetamol and caffeine, the active substances of Temagin Paracetamol plus pass into breast milk. Since the consequences for the infant are not yet known, during short-term use of the recommended doses, there is usually no need to interrupt breastfeeding. The condition and behavior of the infant may be affected by the caffeine excreted with breast milk. With prolonged use or in case of taking higher doses, it should be discontinued.

Driving and using machines

Temagin Paracetamol plus has no influence on the ability to drive or use machines. However, after taking an analgesic, caution should always be taken.

3. HOW TO TAKE TEMAGIN PARACETAMOL PLUS

Always take this medicine as prescribed in this leaflet or as advised by your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

The recommended dose is:

Body weight	Single dose (as number of tablets)	Maximum daily dose (as number of tablets)
Over 43 kg	1 - 2 tablets	8 Tablets
Children and adolescents age 12 years and over, and adults	(350 – 700 mg paracetamol and 50 - 100 mg caffeine)	(corresponding to 2,800 mg paracetamol and 400 mg caffeine)

The respective dosage interval depends on the symptoms and the maximum total daily dose. It should not be less than 6 hours.

Method of administration

For oral use.

Take the whole tablet with plenty of fluid.

Taking this medicine after a meal can lead to delayed onset of action.

Duration of use

Do not take Temagin Paracetamol plus without the advice of a doctor or dentist for more than 3 days. If symptoms persist longer than 3 days, you should consult a doctor.

Special patient groups

Patients with hepatic impairment or mild renal impairment

In patients with hepatic or renal impairment as well as Gilbert's syndrome, the dose must be reduced, or the dosage interval should be extended.

Patients with severe renal impairment

In severe renal impairment (creatinine clearance <10 ml / min) must be adhered to a dose interval of at least 8 hours.

Elderly patients

No special dose adjustment is necessary.

Children

The safety of Temagin Paracetamol plus has not been established in children under the age of 12.

If you take more Temagin Paracetamol plus than you should

Usually, the side effects of paracetamol overdose occur when the maximum daily dose of 60 mg/kg for children and 4,000 mg for adults and adolescents over 12 years old is exceeded.

Within 24 hours, symptoms such as nausea, vomiting, anorexia, pallor and abdominal pain may occur. Severe liver damage can also occur.

Tell your doctor if you have taken a larger amount of paracetamol.

Caffeine overdose can cause symptoms in the central nervous system (e.g., agitation, irritability, tremors) and cardiovascular reactions (e.g., palpitations, pain in the cardiac area).

If you forget to take Temagin Paracetamol plus

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this drug can cause side effects, although not everybody gets them.

Taking a painkiller for headaches too often or for too long can make them worse. Very rare cases of serious skin reactions have been reported.

Stop taking Paracetamol/Caffeine 500 mg/65 mg Tablets and see a doctor or go to a hospital straight away if you experience:

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath.
- Allergic skin reactions (which can sometimes be severe and include peeling, blistering and lesions of skin)
- Accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction).
- Breathing problems: These are more likely if you have asthma or have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Unexplained bruising and bleeding.
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Tremor, difficulty sleeping, dizziness, nervousness, restlessness, irritability, anxiety
- Headache, Fast or irregular heartbeat, rapid breathing
- Stomach upset.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (frequency not known) (see section 2).

If any side effects become severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the National Agency of Drugs and Medical Devices website www.akbpm.gov.al/formulari-raportimi. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TEMAGIN PARACETAMOL PLUS

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package.

6. OTHER INFORMATION

What Temagin Paracetamol plus contains

The active substances are: paracetamol and caffeine.

One tablet contains 350 mg of paracetamol and 50 mg of caffeine.

The excipients are: pregelatinised starch, sodium starch glycolate, microcrystalline cellulose, povidone, magnesium stearate.

Content of the pack:

Temagin Paracetamol plus is packaged in box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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