Package leaflet: Information for the user

Paracetamol/Codeïne Eurogenerics 500mg/30mg tabletten
Paracetamol, codeine phosphate hemihydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Paracetamol/Codeïne EG is and what it is used for

Pharmacotherapeutic group
Paracetamol/Codeïne EG is an analgesic that combines the complementary actions of paracetamol and codeine phosphate.

Therapeutic indications
Paracetamol/Codeïne EG is indicated for the symptomatic treatment of acute moderate pain that cannot be controlled with paracetamol alone.

Codeine can be used in children over 12 years of age for short-term relief of moderate pain that cannot be relieved by other pain relievers such as paracetamol alone or ibuprofen alone. This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics, which act to relieve pain. It can be used alone or in combination with other pain relievers such as paracetamol.

2. What you need to know before you take Paracetamol/Codeïne EG

Do not take Paracetamol/Codeïne EG
- If you are allergic to paracetamol, codeine, phenacetin or any of the other ingredients of this medicine (listed in section 6).
- Without the advice of your doctor if medical tests show that you suffer from severe kidney or liver disease, heart or lung disease, anaemia, high intracranial pressure, signs of respiratory failure, acute asthma or cranial trauma.
- If you are a child under 12 years of age.
- If you have phenylketonuria, you should not take the effervescent tablets. This does not apply to the tablets that can be swallowed.
- Children and adolescents under 18 years of age should not take this medicine to relieve pain after surgical removal of the tonsils or adenoids to treat obstructive sleep apnoea.

- If you know that you convert (metabolise) codeine into morphine very quickly.
- If you are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Invented name].

- Paracetamol/Codeïne EG contains paracetamol. Do not exceed the prescribed or recommended doses or prolong treatment. There is a risk of serious liver damage at doses higher than the recommended dose. If your symptoms persist, consult your treating doctor.
- Because of the risk of overdose, do not take other medicines containing paracetamol. This also includes medicines available without a prescription.
- The consumption of alcoholic beverages during treatment is formally advised against.
- Patients who no longer have a gallbladder may experience acute abdominal pain, generally associated with laboratory test abnormalities suggestive of a sphincter of Oddi spasm.
- If you have a productive cough, codeine can interfere with coughing.
- Paracetamol can cause serious and potentially fatal skin conditions. At the first sign of skin rash or any other sign of hypersensitivity, stop using Paracetamol/Codeïne EG and contact your doctor.
- Paracetamol/Codeïne EG should be used with caution and the dose reduced:
    - o In mild to moderate hepatic insufficiency and in moderate to severe renal insufficiency. Do not use Paracetamol/Codeïne EG not in case of severe hepatic insufficiency (see section 2);
    - o If you have glucose-6-phosphate dehydrogenase deficiency (can cause anaemia due to excessive breakdown of blood (haemolytic anaemia));
    - o If you suffer from chronic alcoholism or consume alcohol excessively (3 or more glasses per day);
    - o If you suffer from anorexia, bulimia or extreme thinness (cachexia), or if you suffer from chronic malnutrition;
    - o In case of dehydration or lack of blood volume (hypovolaemia);
    - o If you have epilepsy, because codeine can lower the epileptogenic threshold;
    - o In case of long-term use; this can lead to increased sensitivity in some people to pain, and there is an increased risk of headaches from overuse of drugs;
    - o If you have asthma, as the use of codeine can cause the release of histamine;
    - o If you suffer from hormonal disorders, as codeine can lead to a drop in hormone levels;
    - o If you have a narrowing of the urethra or an enlarged prostate gland, as codeine can cause urine being held in the bladder due to a disruption of bladder emptying (urinary retention);
    - o If you are or have been dependent on painkillers, as prolonged use of Paracetamol/Codeïne EG may lead to physical and psychological dependence.
- Codeine is converted into morphine in the liver by an enzyme. Morphine is the active substance that relieves pain. Some people have an abnormality of this enzyme, which can manifest itself in different ways. In some people, morphine is not produced at all or only in very small amounts, so that it does not provide sufficient pain relief. Other people are at greater risk of serious side effects because a very large amount of morphine is produced. If you experience any of the following side effects, stop taking this medicine and see a doctor immediately: slow or shallow breathing, confusion, drowsiness, small pupils, nausea or vomiting, constipation, loss of appetite.

- 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 and adolescents up to 18 years
- Do not administrate to children under 12 years of age.

- Use in children and adolescents up to 18 years after surgery: Codeine should not be used for pain relief in children and adolescents under the age of 18 who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea.
- Use in children with breathing problems: Codeine is not recommended for children with breathing problems, as the symptoms of morphine toxicity may be worse in these children.

- The rate at which codeine is converted into the active substance in the body can vary from person to person. This means that some people are at greater risk of side effects, while others experience few side effects.

Elderly
- The elderly may be more sensitive to codeine and therefore have a higher risk of side effects. Your doctor will prescribe a lower dose. The dose can be adjusted according to individual needs.
- It is important to note that the risk of kidney and/or liver failure is more common in elderly people.

Other medicines and Paracetamol/Codeïne EG

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

- Paracetamol/Codeïne EG can be taken together with antirheumatic drugs. It may be combined with anticoagulants, but taking 2 g of paracetamol over a longer period of time may increase the risk of bleeding. Therefore, regular medical monitoring is required.
- Consuming alcohol and taking sedatives, other products intended for the treatment of nervous disorders or heavy analgesics are not recommended.
  More particularly, avoid taking Paracetamol/Codeïne EG until 14 days after discontinuing MAO inhibitors.
- Concurrent use of Paracetamol/Codeïne EG and such sedative medicines as benzodiazepines or related drugs increases the risk of drowsiness, breathing difficulties (respiratory depression), coma and can be life-threatening. Therefore, simultaneous use should only be considered when other treatment options are not possible.
- However, if your doctor prescribes Paracetamol/Codeïne EG together with sedative medicines, they should limit the dose and duration of such simultaneous treatment.
- Please inform your doctor of all sedative medicines you are taking and strictly follow the dose recommended by your doctor. It may be helpful to inform your friends or relatives to be aware of the above signs and symptoms. Tell your doctor if you experience such symptoms.
- The action of chloramphenicol can be influenced by paracetamol. However, metoclopramide and oral contraceptives can affect the action of paracetamol.
- Concomitant use of drugs such as buprenorphine, butorphanol, nalbufine, nalorphine, pentazocine may lead to reduced analgesic effect and withdrawal symptoms.
- Caution is advised when using other drugs that may cause drowsiness.
- Other drugs metabolised by the same enzyme or that slow down the activity of that enzyme may reduce the analgesic effect of codeine. These include, in particular certain antidepressants (paroxetine, fluoxetine, bupropion, sertraline, imipramine, cloripramine, amitriptyline, nortriptyline), antipsychotics (chlorpromazine, haloperidol, levomepromazine, thioridazine), celecoxib and dexamethasone (anti-inflammatories), quinidine (for cardiac arrhythmias) and rifampicin (an antibiotic).
- Concomitant use of so-called anticholinergics (used among other things to treat gastrointestinal, urinary, prostate or respiratory disorders) may enhance the inhibitory effect on bowel function intestinal function, and thus risk bringing intestinal function to a halt.
- Concomitant use of phenytoin may lead to a reduced effect of paracetamol and an increased risk of liver damage. If you are taking phenytoin, avoid high doses or prolonged use of paracetamol.
- Use of probenecid and salicylamide may lead to higher concentrations of paracetamol in the blood. Your doctor may adjust the dose of paracetamol.

- Caution should be exercised when paracetamol is used together with enzyme inducers such as barbiturates (e.g. used as sedatives or anaesthetics), isoniazid (used in the treatment of tuberculosis), carbamazepine (used in the treatment of epilepsy), or rifampicin (an antibiotic).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- The paracetamol in Paracetamol/Codeïne EG may falsify certain diagnostic tests (for example, blood sugar levels).

Paracetamol/Codeïne EG with food, drink and alcohol
Do not drink alcohol during paracetamol treatment.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Paracetamol/Codeïne EG contains codeine and paracetamol, should not be used during pregnancy unless your doctor advises you otherwise.

Paracetamol/Codeïne EG is contraindicated while breastfeeding. Do not take codeine when breastfeeding. Codeine and morphine pass into breast milk. If you codeine metabolises very quickly (see section 2), high concentrations can be reached that can be fatal for the infant.

There are no data on the effects of Paracetamol/Codeïne EG on fertility in humans.

Driving and using machines
As this medicine carries the risk of drowsiness and loss of consciousness, attention required.

Paracetamol/Codeïne EG strongly affects your ability to drive and operate machinery. This medicine may make you dizzy or drowsy. If this happens, do not drive vehicles or use tools or machines. Also do not undertake other activities that require prolonged attention.

Paracetamol/Codeïne EG tablets contain sodium.
This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say, essentially ‘sodium-free’.

3. How to take Paracetamol/Codeïne EG

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine should not be used for more than 3 days. If the pain does not improve after 3 days, you should talk to your doctor.
Paracetamol/Codeïne EG should not be taken by children under 12 years of age due to the risk of serious breathing problems.

The recommended dose is:

Adults (weighing more than 50kg):
1 to 2 tablets up to 3 times per day. Always allow at least 6 hours between doses.

- Do not exceed the maximum daily dose of 8 tablets in 24 hours. The maximum daily dose should not exceed 4 g paracetamol and 240 mg codeine per 24 hours.
- For adults weighing less than 50kg, do not exceed the maximum daily dose of 60 mg paracetamol per kg in 24 hours.

- In patients with impaired liver function, the dose must be reduced or the time between doses increased. Patients with liver failure, Gilbert's syndrome or chronic alcohol consumption should not exceed a daily dose of 4 tablets.
- In patients with moderate or severe renal impairment, the dosing interval should be extended. Renal impairment increases the risk of accumulation of paracetamol and codeine. In patients with moderate or severe renal insufficiency, the minimum interval between each administration should be adjusted according to the following schedule:

Creatinine clearance	Dose interval
CrCl 10 to > 50 ml/min	6 hours
CrCl < 10 ml/min	8 Hours

Adolescents weighing more than 50kg
1 to 2 tablets up to 3 times per day. Always allow at least 6 hours between doses.

Children over the age of 12 years and adolescents weighing between 33 and 50kg:
1 tablet up to 4 times per day. Always allow at least 6 hours between doses.
The maximum daily dose should not exceed 60mg/kg paracetamol and 240 mg codeine in 24 hours.

Children under 12 years old or with a body weight less than 33 kg:
Codeine should not be used in children under 12 years of age due to the risk of toxicity. Moreover Paracetamol/Codeïne EG is not suitable for administration to children with a body weight less than 33 kg.

Do not use simultaneously with other paracetamol-containing medicines.

Method of administration:
Swallow the tablets whole (do not chew), with a glass of water or another liquid.

Warning
As with any pain reliever, Paracetamol/Codeïne EG should not be taken in high doses for long periods without medical supervision, especially if the pain lasts longer than a few days.

If you take more Paracetamol/Codeïne EG than you should
If you have taken too much [Invented name], immediately contact your doctor, pharmacist.

The symptoms seen in individuals who have taken excess doses of codeine phosphate are initially nausea and vomiting. Respiratory depression leads to blue-coloured skin, slowed breathing, falling asleep, lack of coordination and, more rarely, pulmonary congestion. It can also be accompanied by a rash, pain or itchy skin. In more extreme cases, pauses in breathing, convulsions, constricted pupils, facial swelling, general collapse and urinary retention have been reported.

The symptoms associated with taking doses of paracetamol that are too high are nausea, vomiting, loss of appetite, abdominal pain, excess sweating and liver damage. In some individuals, symptoms will only appear a few hours or days after the dose. In this case it is important to determine the number of doses taken by the patient to help the doctor determine the best treatment to follow.

If a massive dose was taken, urgent hospitalisation is necessary.

Notice to the treating doctor
If paracetamol overdose is suspected, the patient should be immediately hospitalised, and serum concentrations should be determined as soon as possible from 4 hours after ingestion.

Values greater than 200 µg/mL at 4 hours or greater than 50 µg/mL at 12 hours may indicate a high risk of hepatic necrosis. The usual liver function tests should be performed early and repeated at regular intervals (24 hours). In most cases, liver transaminase levels return to normal after 1 to 2 weeks, with full recovery of liver function. However, in very severe cases, liver transplantation may be required. However, in very severe cases, liver transplantation may be required.
To avoid the risk of overdose, check that other medicines administered (prescription or non-prescription) do not contain paracetamol.
Administration of paracetamol in higher doses than recommended carries a risk of very serious liver damage. The first clinical symptoms of liver damage are usually observed 1 or 2 days after paracetamol overdose. Maximum symptoms of liver damage are usually observed after 3 to 4 days. An antidote should be administered as soon as possible.
To avoid the risk of overdose or serious side effects, check whether other medicines administered (prescription or non-prescription) do not contain opiates or other suppressors of the central nervous system.

In case of overdose, the stomach should be emptied as soon as possible, i.e. within the first 10 hours, by gastric lavage or by induction of vomiting. Treatment can be started with the administration of activated charcoal, but the main therapeutic measure is the intravenous administration of N-acetylcysteine (NAC).

Two protocols have been validated for the use of NAC in paracetamol overdose, one by intravenous route, the other by oral route.
Intravenous administration has the advantage of always being possible, even in cases of coma or vomiting. This also allows for the oral administration of activated charcoal, without the risk of interfering with the NAC. 20-hour treatment:
In 3 phases:

- Loading dose: 150mg/kg in 250mL 5% glucose over 30 to 60 minutes
- Then 50mg/kg in 500mL 5% glucose over 4 hours
- Then 10mg/kg in 1,000mL 5% glucose over 16 hours.

48-hour treatment:
In cases of particularly severe overdose or if paracetamol was taken more than 10 hours previously, NAC can be administered for 48 hours according to the following schedule:

- Loading dose: 140mg/kg in 5% glucose over 1 hour
- 70mg/kg every 4 hours, each dose should be administered over 1 hour.

The doses specified in this protocol apply to both adults and children.
If NAC is administered orally, activated charcoal cannot be given, as it may interfere with the NAC. -

- Loading dose: 140mg/kg NAC (in a 5% solution in water or fruit juice)
- Maintenance dose: 70mg/kg every 4 hours, repeated 17 times (i.e., over 68 hours).

Early, regular monitoring (every 24 hours) of liver function is strongly recommended.

If you forget to take Paracetamol/Codeïne EG
Do not take a double dose to make up for a forgotten dose.
Take Paracetamol/Codeïne EG as soon as you think of it and wait at least 4 hours before taking the following tablet.

If you stop takingParacetamol/Codeïne EG
During long-term treatments or at supratherapeutic doses, codeine may cause a risk of dependence and withdrawal symptoms upon discontinuation of treatment.
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 medicine can cause side effects, although not everybody gets them.

The paracetamol contained in Paracetamol/Codeïne EG may cause allergic reactions of the skin (such as redness, rash or itching) as well as allergic reactions in the respiratory tract in hypersensitive individuals. If allergic reactions appear, the medicine should be stopped immediately.

The following adverse reactions have been reported after marketing:

Blood and lymphatic system disorders:
Uncommon:
Blood disorders with symptoms such as bruising and bleeding (thrombocytopenia), a blood disorder manifesting as increased susceptibility to infections (leukopenia), an insufficient number of white blood cells that manifests as increased susceptibility to infections (neutropenia).

Immune system disorders:
Uncommon:
Allergic reactions; severe allergic reaction to certain substances, with a sharp drop in blood pressure, pallor, agitation, weak rapid pulse, clammy skin and decreased consciousness due to a sudden strong vasodilatation (anaphylactic shock); sudden accumulation of fluid in the skin or mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (quincke oedema); hypersensitivity.

Metabolism and nutrition disorders:
Not known: a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Psychiatric disorders:
Rare: confusion.
Uncommon: drug abuse, drug addiction, hallucinations.

Nervous system disorders:
Uncommon: dizziness, sudden muscle contractions (myoclonus, paresthesia), tremors, fainting, seizures/convulsions.
Common: drowsiness.

Eye disorders:
Uncommon: pupil constriction (miosis).

Ear and labyrinth disorders:
Uncommon: dizziness, coordination problems (ataxia).

Vascular disorders:
Uncommon: hypotension.

Respiratory, thoracic and mediastinal disorders:
Uncommon: breathing difficulties (bronchospasm), respiratory insufficiency (respiratory depression).

Gastrointestinal disorders:
Common: diarrhoea, constipation, nausea, vomiting.
Uncommon: abdominal pain, inflammation of the pancreas, with symptoms of severe pain in the upper abdomen radiating to the back, nausea and vomiting (pancreatitis); disturbed digestion with a feeling of fullness or stomach discomfort, nausea, vomiting and heartburn (dyspepsia).

Hepatobiliary disorders:
Uncommon: gallstones (with pain in the upper right side of the body, radiating to the shoulder), liver inflammation (hepatitis), elevated liver enzymes.

Skin and subcutaneous tissue disorders:
Uncommon: breathing difficulties and/or itching and rash, often as an allergic reaction (quincke oedema), redness of the skin (erythema), itching (pruritus), rash that may be accompanied by intense itching and urticaria, skin condition characterised by the sudden appearance of hundreds of small vesicles (acute generalised exanthematous pustulosis), sudden severe allergic reaction with symptoms of fever and vesicles on the skin, and desquamation of the skin (toxic epidermal necrolysis), severe allergic reaction with high fever, vesicles on the skin, joint pain and/or inflammation of the eye (stevens-johnsons syndrome). Very rare cases of severe skin reactions were reported.

Musculoskeletal and connective tissue disorders:
Uncommon: muscle breakdown, with symptoms of muscle cramps, fever and reddish-brown discolouration of the urine (rabdomyolysis).

Renal and urinary disorders:
Uncommon: renal insufficiency, retention of urine in the bladder due to interference with urination (bladder emptying).

General disorders and administration site conditions:
Uncommon: weakness (asthenia), general malaise, fluid retention (oedema).

Investigations:
Uncommon: increased transaminase levels, increased aspartate aminotransferase levels, increased levels of alkaline phosphatase in the blood, increased amylase levels in the blood, increased gamma glutamyltransferase levels, accelerated blood coagulation (lowered International Normalised Ratio INR)), delayed blood coagulation (increased International Normalised Ratio (INR)).

The frequency and severity of these side effects depend on the duration of treatment, the dose and the patient's individual sensitivity.

Very rare cases of serious skin reactions have been reported. If you develop a skin rash, stop taking this medicine and talk to your doctor immediately.

If in doubt, ask your doctor or your pharmacist for advice.

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 directly via the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol/Codeïne EG

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paracetamol/Codeïne EG contains

- The active substances are paracetamol and codeine phosphate hemihydrate. Each tablet contains 500mg paracetamol and 30 mg codeine phosphate hemihydrate.

- The other ingredients are: Pregelatinised maize starch, Lactose monohydrate, Talc (E553b), Cellulose powdered (E460), Povidone K30 (E1201), Magnesium stearate (E572), Stearic acid (E570).

What Paracetamol/Codeïne EG looks like and contents of the pack

Description

Paracetamol/Codeïne EG 500mg/30mg, tablets: White to almost white, capsule-shaped, flat tablet with bevelled edge. There is 'PC2' debossed on one side and a score line on the other side of the tablet. Approximate dimension of the capsule-shaped tablets are 17,5 mm diameter and 7 mm thickness.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Contents of the pack

Paracetamol/Codeïne EG tablets are presented in Alu PVC blister packs, in boxes of 16, 16x1, 30 and 30x1 tablets.

Not all pack sizes may be marketed.

In het register ingeschreven onder RVG 131517

Houder van de vergunning voor het in de handel brengen
EG N.V.
Heizel Esplanade B22
1020 Brussel
België

Fabrikant
Santa S.A.
Strada Panselelor 25-29
500419 Brasov
Romenië

Deze bijsluiter is voor het laatst goedgekeurd in april 2025.

The latest approved package leaflet on this medicine is available by scanning the QR code in the outer packaging with a smartphone/device. The same information is also available at the following URL: