Package leaflet: Information for the patient

Paracetalgin 1000 mg, tabletten

paracetamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What <Product name> is and what it is used for

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

<Product name> is used for symptomatic treatment of mild to moderate pain and/or fever.

<Product name> is indicated in adults and adolescents aged 16 years and over.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take <Product name>

Do not take:
- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
To avoid overdose tell your doctor if you are taking other paracetamol containing products. Your doctor will adjust the dosage, in order to avoid the risk of overdose.

Do not take any other paracetamol-containing products.

Talk to your doctor or pharmacist before using <Product name> if you:
- have liver or kidney problems
- are underweight or malnourished
- regularly drink alcohol
- are suffering from impaired liver function (liver inflammation, Gilbert’s syndrome (Meulengracht’s disease))
- have acute hepatitis

- have an enzyme deficiency (glucose-6-phosphate dehydrogenase deficiency)
- have a glutathione (antioxidant) deficiency
- have abnormal breakdown of red blood cells (haemolytic anameia)
- are suffering from dehydration
- are elderly
- have a severe infection as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
    - deep, rapid, difficult breathing
    - feeling sick (nausea), being sick (vomiting)
    - loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.
You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Headaches, as well as fatigue, dizziness, muscle pain, nervousness may occur after sudden discontinuation of prolonged use, high-dose of painkillers such as paracetamol. In that event, ask your doctor or pharmacist for advice.

Children and adolescents
<Product name> must not be given to adolescents under the age of 16. The medicinal product is intended for use in adults and adolescents over the age of 16.

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines; particularly colestyramine (to lower blood cholesterol).
Paracetamol may increase the effect of blood thinning medicines (anticoagulants e.g. warfarin). If you take blood thinning medicines and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding. However you can still take occasional doses of <Product name> at the same time as anticoagulants.
Paracetamol dose should be reduced with concomitant intake of probenecid as this inhibits the binding of paracetamol to glucuronic acid, leading to a reduction in paracetamol clearance.
<Product name> should be administered with zidovudine (AZT) only on medical advice due oo the susceptibility of neutropenia development and liver damage increasing.
Please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
Particular caution should be exercised with concomitant intake of medicines that lead to enzyme induction, as well as with potentially hepatotoxic substances, e.g. phenytoine, carbamazepine, phenobarbital, primidone and rifampicine.
Concomitant intake of agents which slow gastic emptying as the absorption an donset of action of paracetamol may be delayed and agents which accelerate gastric emptying, e.g. metoclopramide, as it speeds up onset of action and absorption. Your doctor or pharmacist should also be advised if domperidone (for nausea [feeling sick] or vomiting [being sick]) has been taken.
Paracetamol may also reduce the effects of lamotrigine, a drug used to treat epilepsy.

Effects on laboratory results
Intake of paracetamol can effect uric acid tests using phosphotungstic acid and blood sugar tests using glucose oxidase-peroxidase.

<Product name> with alcohol
Alcohol should not be used during the treatment with paracetamol.

Pregnancy and breast-feeding

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

If necessary, <Product name> can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your <doctor> if the pain and/or fever are not reduced or if you need to take the medicine more often.

<Product name> in recommended doses may be used during breast-feeding.

There are no adequate clinical data available on male or female fertility.

Driving and using machines
<Product name> has no or negligible influence on the ability to drive and use machines.

3. How to take <Product name>

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The analgesic and antipyretic efficacy of paracetamol in humans is related to the dose administered. The oral dose is based upon age and body weight (BW); the usual single dose is 10 – 15 mg/kg BW up to a maximum of 60 mg/kg (BW) as the total daily dose. In each case, the dosing interval depends on the symptoms and maximum total daily dose. It should be no less than 4 hours.

The lowest dose necessary to achieve efficacy should be used.

Do not exceed the stated dose.

The tablet can be divided into equal doses.

Body weight (age)	**Single dose (equivalent paracetamol dose) (number of tablets)**	**Max. daily dose (24 h) (equivalent paracetamol dose) (number of tablets/doses**	**Minimum interval between doses**
>55 kg (adults and adolescents from 16 years of age)	500 mg – 1,000 mg (½ - 1 tablet)	3,000 mg (maximum of 3 tablets/ 3-6 doses)	4 – 6 hours

Not recommended for children under 16 years of age.

If symptoms persist for more than 3 days or in case of high fever or signs of infection consult your doctor or pharmacist.

Elderly patients
Dose adjustment is not required in the elderly. However, it should be taken into account that renal and/or hepatic insufficiency is more common in the elderly.

Renal impairment
Paracetamol should be used with caution in the presence of renal insufficiency and increased interval between doses is recommended in case of severe renal insufficiency. Where creatinine clearance is between 10-50 ml/min, the minimum interval between administrations should be 6 hours. When creatinine clearance is lower than 10 ml/min, the minimum interval between two administrations should be 8 hours.

A daily dose of 2,000 mg should not be exceeded, for adults, without medical advice.

Hepatic impairement
Paracetamol should be used with caution in the presence of hepatic insufficiency or Gilbert's syndrome. The dose should be reduced or the dosing interval prolonged.

A daily dose of 2,000 mg should not be exceeded, for adults, without medical advice.
Without medical advice, a maximum daily dose of 60 mg/kg body weight (till a maximum of 2,000 mg/day) should not be exceeded in the case of:
- Body weight below 50 kg
- Liver impairment
- Gilbert's syndrome (familial non-haemolytic jaundice)
- Chronic alcohol abuse
- Dehydration
- Chronic malnutrition

Chronic alcohol consumption or impaired liver function may lower the paracetamol toxicity threshold. In these patients, the dose must be reduced or the dosing interval prolonged. Ask your doctor or pharmacist for advise.

Method of administration
Oral use.
The tablet should be swallowed with a glass of water.

If you take more <Product name> than you should
Seek **immediate** medical advice in the event of an overdose, even if you feel well, because of the risk of delayed, serious and irreversible liver damage.

If you forget to take <Product name>
Do not take a double dose to make up for a forgotten tablet.

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.

Rare cases (may affect up to 1 in 1,000 people) include:
- urticaria (hives), itchy skin, rashes
- elevation of liver transaminases.
- liver failure, dysfunction and necrosis (death of liver cells)
- jaundice, with symptoms like yellowing of the skin and eyes)
- sweating
- angioedema (abnormal accumulation of fluid under the skin)
- headache
- dizziness
- generally feeling unwell (malaise)
- gastrointestinal disturbances such as abdominal pain, diarrhea, nausea, vomitting and constipation

Very rare cases (may affect up to 1 in 10,000 people) of serious skin reactions have been reported.
Stop taking this medicine and tell your doctor **immediately** if you experience any of the following:
- serious skin reactions, very rare cases of which have been reported

- allergic reactions such as skin rash or itching, sometimes with breahing problems or swelling of the lips, tongue, throat or face
- severe skin rash or peeling of the skin which may be accompanied by mouth ulcers
- you may have previously experienced breathing problems or bronchospasm with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction to this product
- unexplained bruising or bleeding
- anaphylaxis
- dizziness, weakness, abnormal paleness of the skin, yellowish skin, eyes and mouth, confusion, headaches, high temperature, chills and shivering, sore throat, mouth ulcers that keep returning as these might be symptoms of low blood cell count disorders (agranulocytosis, leukopenia, neutropenia, pancytopenia) or other blood cell disorders (haemolitic anaemia)
- toxic liver disease
- sterile puria (cloudy urine)

The frequency of the following side effects is **not known** (cannot be estimated from the available data):
- skin reactions such as rash (exanthema).
- hepatitis
- nephropathies (interstitial nephritis, tubular necrosis) following prolonged use of high doses
- anaemia

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 <Product name>

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 blister and 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 <Product name> contains
The active substance is paracetamol. Each tablet contains 1000 mg paracetamolThe other ingredients are
starch, pregelatinized (maize), calcium carbonate, povidone (K-25), crospovidone (type B), alginic acid, silica, colloidal anhydrous, magnesium stearate

What <Product name> looks like and contents of the pack

<Product name> is white to off-white, oval shaped biconvex tablet, breakline on both sides of the tablet. The tablet is approximately 9.2 x 22.0 mm in size with a height of approximately 7.0-8.5 mm.

The tablet can be divided into equal doses.

<Product name> is packed in PVC/PVdC-Aluminium-paper blisters and OPA/Alu/PVC-Aluminium blisters, available in pack sizes 10, 15, 20 and 30 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Teva B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Fabrikant
Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Merckle GmbH
Graf-Arco-Str. 3
89079 Ulm
Duitsland

In het register ingeschreven onder
RVG 127230

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Oostenrijk:	Paracetamol ratiopharm 1000 mg Tabletten
België:	Paracetamol Teva Fasttabs 1 g tabletten/comprimés/Tabletten
Finland:	Paracetamol Teva 1000 mg tabletti
Duitsland:	Paracetalgin
Portugal:	Paracetamol Teva
Roemenië:	Paracetamol Teva 1000 mg, comprimate
Nederland:	Paracetalgin 1000 mg, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in mei 2022.