PACKAGE LEAFLET - 1000 mg

Package leaflet: Information for the user

Paracetamol Neogen 1000 mg filmomhude tabletten
Paracetamol

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 /.../ is and what it is used for

/…/ contains active substance paracetamol which belongs to a group of medicines called analgesics (painkillers).

/.../ may be used in adults and children weighing more than 55 kg (i.e. about 15 years).

This medicinal product is not considered suitable for children weighing less than 55 kg. Ask your pharmacist or doctor for advice.

/.../ is used to relieve pain and help reduce fever. The tablets can treat mild to moderate pain and/or fever.

2. What you need to know before you use /.../

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

Warnings and precautions
Talk to your doctor before taking /.../:
- if you are taking other paracetamol containing medicines, as it may severely damage the liver.
- if you have liver problems (including Gilbert's syndrome or acute hepatitis).
- If you have impaired kidney function.
- if you have a deficiency of a certain enzyme called glucose-6-phosphatase.
- if you have haemolytic anaemia (abnormal breakdown of red blood cells).
- if you have a poor nutritional status, for example as a result of alcohol abuse, loss of appetite (anorexia), or malnutrition. You may have to take a lower dose, otherwise your liver may become damaged.
- if you are asthmatic sensitive to acetylsalicylic acid.
- if you have a high temperature, signs of infection (e.g. sore throat) or if the pain lasts longer than 3 days.
- if you drink alcohol.

This medicinal product contains paracetamol. Do not use other medicinal products containing paracetamol at the same time, you may get kidney damage with the risk of kidney failure.

If you take /.../ for headaches for a long period, your headaches may become worse and more frequent. Contact your doctor if you have frequent or daily headaches.

If you are providing a blood or urine sample, always mention that you are being treated with /.../. It may affect the results.

Children and adolescents
/.../ should not be given to children weighing less than 55 kg. Ask your pharmacist or doctor for advice.

Other medicines and /.../
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, medicines purchased abroad, alternative medicines as well as potent vitamins and minerals.
Do not use /.../ in combination with other paracetamol-containing medicines.

Talk to your doctor if you are taking:
- Medicines used to treat nausea and vomiting (metoclopramide or domperidone)
- Medicines used to lower your cholesterol (cholestyramine)
- Medicines for epilepsy (such as phenytoin, carbamazepine and lamotrigine).
- Medicines for gout (probenecid). The dose may need to be changed.
- Blood thinners (e.g. warfarin and other coumarin derivatives). You may have bleeding, if you take /.../ regularly over a long period of time.
- Salicylamide (a pain killer)
- Medicines used to treat tuberculosis (isoniazid or rifampicin)
- Medicines that cause relaxation and sleepiness (barbiturates or carbamazepines)
- A medicine used to treat depression (St. John's Wort)
- Chloramphenicol (an antibiotic)
- Zidovudine (a medicine used to treat AIDS)
- 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.

If you are going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that you are taking this medicine as it could affect the results of these tests.

If you are taking medication for high cholesterol (cholestyramine), you should take /.../ at least 1 hour before or 4 to 6 hours after this medication. Talk to your doctor.

/.../ with food, drink and alcohol
You can take /.../ with a meal, although it is not necessary.
You should take /.../ tablets with a glass of water.
It is advised not to drink large amounts of alcohol when taking /…/.

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.

Pregnancy

If necessary, /…/ can 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Breast-feeding
Although paracetamol is excreted in the breast milk in small amounts it has no unwanted effects on the child that is breast fed. You can breastfeed even if you take /.../ as long as the recommended dosage is not exceeded. In case of long term use caution should be exercised.

Fertility
No detrimental effects on fertility upon normal use of paracetamol are known.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
/.../ does not affect the ability to work safely or the ability to drive safely in traffic.

3. How to take /.../

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

The recommended dose is:
Use in adults and children above 15 years
½ to one tablet of 1000 mg at a time, up to 3 tablets (3000 mg) per 24 hours. The dosing interval should be at least 4 hours.
The 1000 mg strength is not considered suitable for children below 55 kg (i.e. about 15 years).

- Do not use in combination with other paracetamol-containing preparations.
- Do not exceed the stated dose.
- If your symptoms of pain and/or fever return, you may repeat the treatment with /…/
- If you do not feel better or if you feel worse after 3 days, or if other symptoms appear, you should stop the treatment and consult a doctor.

Renal impairment
In case of renal insufficiency (renal failure), the dose should be reduced. Talk to your doctor or pharmacist.

Hepatic impairment
In patients with hepatic impairment or Gilberts syndrome, the dose must be reduced or the dosing interval prolonged. Talk to your doctor or pharmacist.

The effective daily dose should not exceed 60 mg/kg/day (up to 2000 mg/day) in the following situations:
- Adults weighing less than 50 kg
- Mild to moderate hepatic insufficiency, Gilbert's syndrome (familial non-haemolytic jaundice)
- Dehydration
- Chronic malnutrition
- Chronic alcoholism

Follow these instructions unless your doctor has given you different advice.
If you feel that /…/ is too strong or too weak, talk to your doctor or pharmacist.

<u>Method of administration</u>
Swallow the tablet with a glass of water.

The tablet can be divided into equal doses.

If you take more /.../ 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 liver damage**. Symptoms of paracetamol overdose are nausea, vomiting and reduced appetite. Unconsciousness does not usually occur.

If you forget to take /.../
Do not take a double dose to make up for a forgotten dose. Just continue with your recommended 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 medicine can cause side effects, although not everybody gets them.
Possible side effects are listed below and classified as:

Rare side effects (affects 1 to 10 users in 10,000)
- Several blood disorders including agranulocytosis, thrombocytopenia, thrombocytopenic purpura, hemolytic anemia leukopenia platelet disorders (clotting disorders) and stem cell disorders (disorders of the blood forming cells in bone marrow).
- Allergic reactions.
- Depression, confusion, hallucinations.
- Tremor, headache.
- Disturbed vision.
- Oedema (abnormal accumulation of fluid under the skin).
- Abdominal pain, stomach or intestinal bleeding, diarrhoea, nausea, vomiting.
- Abnormal liver function, liver failure, jaundice (with symptoms like yellowing of the skin and eyes), hepatic necrosis (death of liver cells).
- Rash, itching, sweating, hives, red patches on skin, angioedema with symptoms like swollen face, lips, throat or tongue.
- Dizziness, generally feeling unwell (malaise), fever, sedation, interactions with medicines.
- Overdose and poisoning.

Very rare side effects (affects less than 1 user in 10,000):
- Pancytopenia (reduction in the number of blood cells).
- Allergic reactions where treatment should be stopped, including angioedema, difficulty breathing, sweating, nausea, hypotension, shock, and anaphylaxis.
- Low level of blood glucose in the blood.
- Hepatotoxicity (damage caused to the liver due to chemicals).
- Cloudy urine and kidney disorders.
- Bronchospasm (difficulty in breathing) in patients sensitive to aspirin and other anti-inflammatory medicines.
- Haematuria (blood in urine).
- Anuresis (inability to urinate).

Not Known (frequency cannot be estimated from the available data):
- Acute generalised exanthemateus pustulosis (drug eruption characterized by numerous small, primarily non-follicular, sterile pustules).
- Severe skin rash or peeling of the skin.
- Stevens–Johnson syndrome (a severe life-threatening skin disorder).
- Reddening of skin, blisters or rash due to intake of paracetamol.

Once you stop taking the medicine these side effects should go away. If any of the side effects gets serious, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in <[To be completed nationally]>. By reporting side effects you can help provide more information on the safety of this medice.

5. How to store /.../

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. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

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 /.../ contains
- The active substance is paracetamol.
- The other ingredients are pregelatinised starch, corn starch, povidone, stearic acid, talc.
  Film-coating: Opadry White (Y-1-7000): Hypromellose, macrogol, titanium dioxide (E171)

What /.../ looks like and contents of the pack
/.../ 1000 mg tablets are white, film-coated, oval tablets that have a break line on one side and are plain on the other side.

The film-coated tablets are packed in PVC/Aluminium blisters and HDPE bottles with screw cap.

Package sizes
8, 20 and 30 film-coated tablets in blisters.
100 film-coated tablets in bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Neogen N.V.
Square Marie Curie 50
1070 Anderlecht
België

Manufacturer
SANTA S.A.
Str. Panselelor nr. 25, nr. 27, nr. 29,
Brasov, jud. Brasov, 500419,
Romania

In het register ingeschreven onder
RVG 118558

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in November 2022.