

Package leaflet: Information for the user

Paracetamol Zentiva 500 mg tablets

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 has 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 (in case of fever) or 5 days (in case of pain).
- Do not give the product to children for more than 3 days without consulting a doctor.

What is in this leaflet

1. What Paracetamol Zentiva is and what it is used for
2. What you need to know before you take Paracetamol Zentiva
3. How to take Paracetamol Zentiva
4. Possible side effects
5. How to store Paracetamol Zentiva
6. Contents of the pack and other information

1. What is Paracetamol and what is it used for

The name of your medicine is Paracetamol Zentiva 500mg tablets (called Paracetamol Zentiva throughout this leaflet).

This product contains paracetamol, active substance relieving fever and pain.

Paracetamol Zentiva tablets are used for short-term symptomatic treatment of mild to moderate pain such as headache, toothache, menstrual pain, muscle and joint pain during flu and cold, and/or fever.

Paracetamol Zentiva 500mg is intended for adults, adolescents and children with body weight above 21 kg (aged 6 years and over).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days (for fevers) or 5 days (for pain).

Do not give the product to children for more than 3 days without consulting a doctor.

2. What you need to know before you take Paracetamol Zentiva

Do not take Paracetamol Zentiva if you:

- are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).
- have severe hepatic impairment.
- have acute liver inflammation.

Warnings and precautions

Contains Paracetamol. Do not use Paracetamol Zentiva with other medicinal products containing paracetamol.

Do not exceed the stated dose.

Use of higher than recommended doses may lead to the risk of severe liver damage.

Do not drink alcoholic beverages when taking this medicine.

Talk to your doctor or pharmacist before taking Paracetamol Zentiva if you

- suffer from a liver disease.
- suffer from a kidney disease.
- abuse alcohol.
- have deficiency of enzyme glucose-6-phosphate dehydrogenase.
- suffer from low count of red blood cells caused by their abnormal breakdown (haemolytic anaemia).
- are elderly.
- are dehydrated or malnourished.

Caution is necessary if you suffer from severe infection, which can lead to metabolic acidosis.

Signs of metabolic acidosis are:

- deep, accelerated, difficult breathing,
- nausea (feeling sick), vomiting,
- loss of appetite.

If you experience a combination of these symptoms, contact your doctor immediately.

Do not take this medicine without your doctor's advice if you have problems with drinking alcohol.

Children and adolescents

Due to the amount of active substance in the tablet, Paracetamol Zentiva 500 mg is not intended for children under 6 years of age with body weight less than 21 kg.

Other medicines and Paracetamol Zentiva

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

Do not use Paracetamol Zentiva with other medicinal products containing paracetamol.

The effects of paracetamol and the effects of other medicines you are taking at the same time may interact.

Ask your doctor or pharmacist for advice before taking Paracetamol Zentiva if you are taking any of the following medicines:

- Some medicines reducing blood clotting (e.g. warfarin).
- Medicines for nausea and vomiting (e.g. metoclopramide or domperidone) or medicine reducing the cholesterol level (cholestyramine).
- Acetylsalicylic acid, other pain and fever-relieving medicines belonging to the group of non-steroidal anti-inflammatory drugs (NSAID).
- Some antibiotics (rifampicin, chloramphenicol).
- Some medicines used to treat gout (probenecid).
- Some medicines used to treat epilepsy (phenobarbital, phenytoin, carbamazepine).
- Herbal remedies containing St. John's Wort.
- Zidovudine (used to treat HIV infection).
- Isoniazid (used to treat tuberculosis).
- 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.

Paracetamol Zentiva with food, drink and alcohol

Do not drink alcoholic beverages when taking this medicine. Long-term alcohol consumption significantly increases the liver damage risk. If you have problems with drinking alcohol, talk to your doctor before starting treatment with Paracetamol Zentiva.

Pregnancy and breast-feeding

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.

If necessary, Paracetamol Zentiva 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.

Paracetamol Zentiva passes into breast milk but is unlikely to affect breast-fed babies. It is not necessary to stop breast-feeding during short-term treatment with the recommended doses of this medicinal product.

Driving and using machines

Paracetamol Zentiva has no influence on the ability to drive or use machines.

3. How to use Paracetamol Zentiva

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

Dosage is as recommended in the table below:

| Approximate age | Body weight | Single dose | Maximum daily dose |
|-----------------|-------------|-------------------------------|--------------------|
| 6 – 8 years | 21 – 24 kg | ½ tablet (250 mg) | 2 tablets (1 g) |
| 9 – 10 years | 25 – 33 kg | ½ tablet (250 mg) | 3 tablets (1.5 g) |
| 10 – 12 years | 34 – 41 kg | 1 tablet (500 mg) | 4 tablets (2 g) |
| 12 – 15 years | 42 – 49 kg | 1 tablet (500 mg) | 5 tablets (2.5 g) |
| over 15 years | 50 – 60 kg | 1 tablet (500 mg) | 6 tablets (3 g) |
| | over 60 kg | 1 – 2 tablets (500 – 1000 mg) | 6 tablets (3 g)* |

* Maximum daily dose of 8 tablets (4 g) can be taken in patients with body weight over 60 kg only after consultation with a doctor.

Single dose may be repeated as needed, with an interval of at least 4 – 6 hours.

Paracetamol Zentiva 500mg tablets are not intended for children less than 6 years of age with body weight less than 21 kg.

In patients with impaired kidney or liver function, the doctor will determine the dose.

Do not exceed the recommended dosage.

Warning: Taking higher than recommended doses may lead to a risk of severe liver damage.

Duration of treatment

If the fever is not reduced within 3 days and the pain is not subsided or the symptoms worsen within 5 days, or if new symptoms occur, consult your doctor for further treatment. Take this medicine without consulting a doctor for a maximum of 7 days.

Do not give the product to children for more than 3 days without consulting a doctor.

Method of administration

The tablets should be swallowed with a sufficient amount of liquid.

The tablets can be divided into equal doses.

Paracetamol Zentiva can be taken with or without food.

If you take more Paracetamol Zentiva than you should

Overdose may be manifested by nausea, vomiting or paleness. In all cases of suspected overdose or incidental ingestion by a child, seek immediate medical assistance, even if you or the child feel well, because of the risk of delayed, serious and irreversible liver damage. Give them the consumed pack and this leaflet.

If you forget to take Paracetamol Zentiva

Do not take a double dose to make up for a forgotten dose. Take the missed dose as soon as you remember. Any potential next dose should be taken after the interval indicated in section 3 above.

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.

Stop taking the medicine immediately and seek medical assistance without delay if any of the following side effects occur:

- Allergic reactions such as rash or itching (rare – may affect up to 1 in 1,000 people), sometimes accompanied with breathing problems, swelling of lips, tongue, throat or face (very rare – may affect up to 1 in 10,000 people).
- Serious skin reactions including peeling of the skin or blistering in the mouth (very rare – may affect up to 1 in 10,000 people).
- Previous breathing problems after taking acetylsalicylic acid or other painkillers belonging to the group of non-steroidal anti-inflammatory drugs, and you have similar problems after administration of Paracetamol Zentiva (very rare – may affect up to 1 in 10,000 people).
- Unexplained bruising (very rare – may affect up to 1 in 10,000 people).

Other side effects

Very rare (may affect up to 1 in 10,000 people):

- Liver dysfunction.

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:

HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol Zentiva

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 and blister 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 Zentiva contains

- The active substance is paracetamol. Each tablet contains 500 mg of paracetamol.
- The other ingredients are pregelatinised maize starch, maize starch, talc (E 553), stearic acid (E 570) and povidone (E 1201).

What Paracetamol Zentiva looks like and contents of the pack

Paracetamol Zentiva 500 mg are white capsule shaped tablets with flat edges, dimensions approx. 17×7 mm, S score line 1 (S|1) on one side.

Paracetamol Zentiva is packed in PVC/Alu blisters.

Paracetamol Zentiva 500 mg is available in packs of 10, 12, 16, 20 or 24 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Zentiva, k.s., U kabelovny 130, Dolní Měcholupy, 102 37 Prague 10, Czech Republic.

Manufacturer

Zentiva S.A.
Bulevardul Pallady Theodor Nr. 50, Sector 3
Bucharest
032266
Romania

This medicine is authorised in the Member States of the European Economic Area under the following names:

| | |
|--|-----------------------------|
| Czech Republic, Denmark, Estonia, Ireland, Latvia, Lithuania, Norway, Poland, Slovakia, Sweden | Paracetamol Zentiva |
| France | Paracetamol Zentiva LAB |
| Italy | Paracetamolo Zentiva S.r.l. |

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| Romania | Pacetril |
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This leaflet was last revised in December 2023.

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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.

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You must talk to a doctor if you do not feel better or if you feel worse after 3 days (for fevers) or 5 days (for pain).

Do not give the product to children for more than 3 days without consulting a doctor.

2. What you need to know before you take Paracetamol Zentiva

Do not take Paracetamol Zentiva if you:

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- have severe hepatic impairment.
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Warnings and precautions

Contains Paracetamol. Do not use Paracetamol Zentiva with other medicinal products containing paracetamol.

Do not exceed the stated dose.

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Do not drink alcoholic beverages when taking this medicine.

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- suffer from a liver disease.
- suffer from a kidney disease.
- abuse alcohol.
- have deficiency of enzyme glucose-6-phosphate dehydrogenase.
- suffer from low count of red blood cells caused by their abnormal breakdown (haemolytic anaemia).
- are elderly.
- are dehydrated or malnourished.

Caution is necessary if you suffer from severe infection, which can lead to metabolic acidosis.

Signs of metabolic acidosis are:

- deep, accelerated, difficult breathing,
- nausea (feeling sick), vomiting,
- loss of appetite.

If you experience a combination of these symptoms, contact your doctor immediately.

Do not take this medicine without your doctor's advice if you have problems with drinking alcohol.

Children and adolescents

Due to the amount of active substance in the tablet, Paracetamol Zentiva 500 mg is not intended for children under 6 years of age with body weight less than 21 kg.

Other medicines and Paracetamol Zentiva

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- Medicines for nausea and vomiting (e.g. metoclopramide or domperidone) or medicine reducing the cholesterol level (cholestyramine).
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Paracetamol Zentiva with food, drink and alcohol

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Pregnancy and breast-feeding

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.

If necessary, Paracetamol Zentiva 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.

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Driving and using machines

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Warning: Taking higher than recommended doses may lead to a risk of severe liver damage.

Duration of treatment

If the fever is not reduced within 3 days and the pain is not subsided or the symptoms worsen within 5 days, or if new symptoms occur, consult your doctor for further treatment. Take this medicine without consulting a doctor for a maximum of 7 days.

Do not give the product to children for more than 3 days without consulting a doctor.

Method of administration

The tablets should be swallowed with a sufficient amount of liquid.

The tablets can be divided into equal doses.

Paracetamol Zentiva can be taken with or without food.

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Do not take a double dose to make up for a forgotten dose. Take the missed dose as soon as you remember. Any potential next dose should be taken after the interval indicated in section 3 above.

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Other side effects

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5. How to store Paracetamol Zentiva

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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 Zentiva contains

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Paracetamol Zentiva is packed in PVC/Alu blisters.

Paracetamol Zentiva 500 mg is available in packs of 30, 50, 100, 120 or 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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| France | Paracetamol Zentiva LAB |
| Italy | Paracetamolo Zentiva S.r.l. |
| Romania | Pacetral |

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