

PACKAGE LEAFLET: INFORMATION FOR THE USER
Paracetamol Tablets 500mg
from the makers of Disprin
Paracetamol

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Paracetamol Tablets 500mg from the makers of Disprin are and what they are used for

Paracetamol Tablets 500mg contain the active ingredient paracetamol. Paracetamol belongs to a group of medicines known as non-narcotic analgesics, which are used to relieve pain and to lower temperature. Paracetamol Tablets 500mg are indicated for the relief of headaches, musculoskeletal disorders, period pain, toothache, colds and flu and the pain of osteoarthritis.

2. Before you take Paracetamol Tablets 500mg from the makers of Disprin

Do not take Paracetamol Tablets 500mg if you:

- have had an allergic reaction to paracetamol or any of the ingredients listed in section 6. An allergic reaction can include a rash, itching or shortness of breath.
- have a liver disorder.

Not suitable for children under 6 years of age.

Take special care with Paracetamol Tablets 500mg if:

- You have kidney problems
- You have liver problems, including alcoholic liver disease.
- You have a high fever, signs of a secondary infection or if symptoms persist.
- If you are underweight (less than 50 kg) or are malnourished
- If you suffer from severe dehydration
- If you are elderly
- If you have glutathione deficiency (a metabolic disorder which may lead to difficulty in breakdown of paracetamol)
- If you have an enzyme deficiency called Glucose-6-phosphate dehydrogenase deficiency
- If you have haemolytic anaemia (abnormal breakdown of red blood cells)

You may be more at risk of the side effects of paracetamol. Speak to your doctor or pharmacist if any of these apply to you.

Taking other medicines:

You must not take **any other medicines that contain paracetamol** while you are taking this medicine.

You should consult your doctor **BEFORE** taking any other medicines including:

- Other pain relieving medicines (e.g. morphine)
- Drugs used in the treatment of epilepsy
- Drugs used to prevent clotting (e.g. warfarin and other coumarins)
- Anticholinergic drugs which affect the nervous system (e.g. atropine, hyoscine)
- Zidovudine (AZT) used in HIV infections and AIDS
- Metoclopramide or domperidone used for nausea and vomiting
- Cholestyramine (used in high cholesterol)
- Propantheline used for irritable bowel syndrome or in the treatment of stomach ulcers
- Probenecid used in the treatment of gout.
- Medicines to help you sleep (barbiturates)
- Flucloxacillin. 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.
Use of paracetamol may influence some laboratory tests (uric acid and glucose tests). Seek advice from your doctor if you are concerned.

Taking with food and drink

- There is an increased risk of side effects when alcohol is taken in combination with paracetamol.

Pregnancy and breast-feeding:

If necessary, Paracetamol Tablets from the makers of Disprin 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 or pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol is proven to be safe during breast feeding. However, as with all medicines, caution should be taken. Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Paracetamol Tablets 500mg from the makers of Disprin

The following are the usual doses:

Adults, the elderly and children aged 16 years and over: 1 to 2 tablets every 4-6 hours as required. Do not take more than 8 tablets in 24 hours.

In patients over 16 years of age, do not take more than 4 tablets in 24 hours (2g paracetamol/day) in the following situations, unless directed by your doctor:

- Weight less than 50 kg
- Use of large quantities of alcohol regularly (alcoholism)
- Dehydration
- Malnutrition

Use in kidney or liver impairment:

If you have been diagnosed with kidney or liver problems, please consult your doctor or pharmacist. You may need to take a lower dose or increase the length of time between doses.

Paediatric Population

Children under 6 years: Not recommended

Aged 6 to 9 years: ½ tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours

Aged 10 to 11 years: 1 tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours

Aged 12 to 15 years: 1 to 1 ½ a tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours

DO NOT EXCEED THE STATED DOSE.

The tablets should be swallowed with a little water.

Consult your doctor if there is no improvement within 24 hours.

This product should only be used when clearly necessary.

Prolonged use without medical supervision may be harmful.

If you take more Paracetamol Tablets 500mg than you should:

If you accidentally take too many tablets, contact your nearest hospital casualty department or your doctor **IMMEDIATELY**.

IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE, BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE.

If you forget to take Paracetamol Tablets 500mg:

If you forget to take a dose, take it as soon as you remember if required to relieve pain. Do not take two doses together.

4. Possible side effects

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

If you experience any of the following very rare side-effects, stop taking this medicine and seek medical advice immediately.

- Severe allergic reactions which may include skin rashes, flaking skin, boils, sore lips and mouth, swelling of the face, fever, sudden wheezing, fluttering or tightness of the chest, or collapse.
- Skin reactions which may include rashes, itching, fluid build up in tissue below the skin and the mucous membranes which appears as spots and lumps, blood blisters and flaking or changes in skin colour.

- Bruising and bleeding more easily, sore throat or other signs of infection as these may be signs of a serious blood disorder.
- Breathing problems which you may have previously experienced with aspirin or non-steroidal anti-inflammatories.

The following side effects may also occur;

Rare (may affect up to 1 in 1,000 people)

- Abnormal blood test result for liver function

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

- shortness of breath and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma (analgesic drug induced asthma)
- liver disorders may occur

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Tablets 500mg from the makers of Disprin

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use Paracetamol Tablets 500mg after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package in order to protect from moisture. Keep blisters in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Paracetamol Tablets 500mg contain:

Each tablet contains paracetamol 500 mg.

The tablets also contain: maize starch, pregelatinised maize starch, magnesium stearate and colloidal anhydrous silica.

What Paracetamol Tablets 500mg look like and contents of the pack:

Paracetamol Tablets 500mg are white tablets engraved with the code 293 and partial breaklines on one side and a product logo on the reverse.

Pack size: 12 tablets.

Marketing Authorisation holder:

Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturers:

Reckitt Benckiser Healthcare (UK) Ltd.,

Dansom Lane,

Hull HU8 7DS,

UK

Clonmel Healthcare Ltd.,

Waterford Road,

Clonmel,

Co. Tipperary.

Sofarimex,

Av.das Indústrias,

Alto do Colaride/Agualva,

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This leaflet was last revised in Upon approval