

30mm

FLAT DIMENSION = 130 x 430mm
FOLDED DIMENSION = 130 x 27mm

10mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

PARACETAMOL 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 have told you.

- Keep this leaflet. You may need to read it again.
- If you have any further queries, 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 Tablets are and what they are used for
2. What you need to know before you take Paracetamol Tablets
3. How to take Paracetamol Tablets
4. Possible side effects
5. How to store Paracetamol Tablets
6. Contents of the pack and other information

1. What Paracetamol Tablets are and what they are used for

Paracetamol is an analgesic and an antipyretic which means it relieves pain and reduces high temperature (fever).

These tablets are for effective relief from: mild to moderate pain including headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, aches and pain, symptomatic relief of rheumatic aches and pains, influenza symptoms, feverishness and feverish colds.

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

Please read the following information.

Do not take these Tablets if you:

- are allergic to paracetamol or any other ingredients of this medicine (listed in Section 6)
- are taking any other paracetamol-containing products

Warnings and Precautions

Take special care and talk to a pharmacist or your doctor before taking this medicine if you are:

- suffering from liver or kidney disease (including alcoholic liver disease) or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).

During treatment with Paracetamol, tell your doctor straight away 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).

Other medicines and Paracetamol

Please inform your doctor or pharmacist if you are taking:

- medicines that reduce the clotting of the blood (e.g. warfarin).
- some antibiotics (chloramphenicol), anti-sickness treatments (metoclopramide, domperidone), some treatments for diarrhoea caused by gall bladder disease, or lipid lowering drugs (cholestyramine).
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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.

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

Small amounts of paracetamol pass into breast milk. This medicine may be taken, as instructed (see section 3), by mothers who are breastfeeding.

Driving and using machines

Paracetamol is not known to cause any effects on the ability to drive and use machines.

Paracetamol Tablets contain Sodium metabisulfite

Paracetamol tablets contain sodium metabisulfite which may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Paracetamol Tablets

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.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

The breakline is only there to help you break the tablet if you have difficulty swallowing it whole.

The recommended dose is:

Adults, the elderly and children 16 years and over: The minimum effective dose should be used for the shortest time necessary to relieve symptoms. Take one to two tablets every 4-6 hours, if you need to. **Do not take more than 8 tablets** in any 24 hours.

Paracetamol
500 mg tablets
Insert Luton

SAME SIZE ARTWORK
430 x 130mm
Front

Children 10 to 15 years of age: Take one tablet every 4-6 hours, if you need to.

Do not take more than 4 tablets in any 24 hours.

Do not take more often than every 4 hours.

Do not give to children for more than three days without seeing your doctor.

DO NOT GIVE TO CHILDREN UNDER 10 YEARS OF AGE.

Do not take anything else containing paracetamol while taking this medicine.

If you take more Paracetamol Tablets than you should

If you accidentally take more tablets than you should, tell your doctor immediately or go to the nearest hospital A & E (casualty) department. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take a dose

If necessary, take the missed dose when you remember and then leave at least 4 hours before taking the next dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE

4. Possible side effects

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

You can reduce the chances of experiencing side effects by using the minimum dose required. Side effects may be more serious in elderly patients.

If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

- Severe allergic reactions: difficulty breathing, skin rash, swollen facial features or a runny nose.
- Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash.
- Not known (frequency cannot be estimated from the available data) - A serious condition that can

make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- Other rare side effects like shortness of breath.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from moisture.
- Do not use the tablets after the expiry date printed on the carton or label (EXP.). The expiry date refers to the last day of that month.
- 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 Tablets contain

- The active substance is Paracetamol.
- The other ingredients are: pregelatinised maize starch, sodium metabisulfite (E223) and magnesium stearate.

What Paracetamol Tablets looks like and contents of the pack

- The tablets are white, capsule shaped tablets with breakline on one side and plain on the other side.
- They are available in cartons containing 8, 12, 16, 24, 30, 32 or 100 tablets or containers of 16 and 1000 tablets for dispensing purposes.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address:

Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road, Berkhamsted,
Hertfordshire, HP4 1EG, United Kingdom
Telephone: 0044 (0)1442 200922
E-mail: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Ltd
Laporte Way, Luton, LU4 8WL,
United Kingdom

Manufacturer

Bristol Laboratories Ltd
Unit 5, Traynor Way, Whitehouse Business Park,
Peterlee, SR8 2RU, United Kingdom

Paracetamol 500 mg Tablets; PL 17907/0001

This leaflet was last revised in January 2025

To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, fax, email) above.

V17 06-01-25 DO



FLAT DIMENSION = 130 x 430mm
FOLDED DIMENSION = 130 x 27mm

30mm

10mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

PARACETAMOL 500 MG CAPLETS (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.
- If you have any further queries, 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 Caplets are and what they are used for
2. What you need to know before you take Paracetamol Caplets
3. How to take Paracetamol Caplets
4. Possible side effects
5. How to store Paracetamol Caplets
6. Contents of the pack and other information

1. What Paracetamol Caplets are and what they are used for

Paracetamol is an analgesic and an antipyretic which means it relieves pain and reduces high temperature (fever).

These caplets are for effective relief from: mild to moderate pain including headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, aches and pain, symptomatic relief of rheumatic aches and pains, influenza symptoms, feverishness and feverish colds.

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

Please read the following information.

Do not take these Caplets if you:

- are allergic to paracetamol or any other ingredients of this medicine (listed in Section 6)
- are taking any other paracetamol-containing products

Warnings and Precautions

Take special care and talk to a pharmacist or your doctor before taking this medicine if you are:

- suffering from liver or kidney disease (including alcoholic liver disease) or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).

During treatment with Paracetamol, tell your doctor straight away 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).

Other medicines and Paracetamol

Please inform your doctor or pharmacist if you are taking:

- medicines that reduce the clotting of the blood (e.g. warfarin).
- some antibiotics (chloramphenicol), anti-sickness treatments (metoclopramide, domperidone), some treatments for diarrhoea caused by gall bladder disease, or lipid lowering drugs (cholestyramine).
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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.

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

Small amounts of paracetamol pass into breast milk. This medicine may be taken, as instructed (see section 3), by mothers who are breastfeeding.

Driving and using machines

Paracetamol is not known to cause any effects on the ability to drive and use machines.

Paracetamol Caplets contain Sodium metabisulfite

Paracetamol caplets contain sodium metabisulfite which may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).

Information on Sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per caplet, that is to say essentially “sodium free”.

3. How to take Paracetamol Caplets

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.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

The breakline is only there to help you break the caplet if you have difficulty swallowing it whole.

The recommended dose is:

Adults, the elderly and children 16 years and over: Take one to two caplets every 4-6 hours, if you need to.

Do not take more than 8 caplets in any 24 hours.

Children 10 to 15 years of age: Take one caplet every 4-6 hours, if you need to.

Do not take more than 4 caplet in any 24 hours.

Paracetamol
500 mg Caplets
Insert Luton

SAME SIZE ARTWORK
430 x 130mm
Front

XXXX

Do not take more often than every 4 hours.

Do not give to children for more than three days without seeing your doctor.

DO NOT GIVE TO CHILDREN UNDER 10 YEARS OF AGE.

Do not take anything else containing paracetamol while taking this medicine.

If you take more Paracetamol Caplets than you should

If you accidentally take more caplets than you should, tell your doctor immediately or go to the nearest hospital A & E (casualty) department. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take a dose

If necessary, take the missed dose when you remember and then leave at least 4 hours before taking the next dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE

4. Possible side effects

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

You can reduce the chances of experiencing side effects by using the minimum dose required. Side effects may be more serious in elderly patients.

If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

- Severe allergic reactions: difficulty breathing, skin rash, swollen facial features or a runny nose.
- Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash.
- Not known (frequency cannot be estimated from the available data) - A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- Other rare side effects like shortness of breath.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Pages in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol Caplets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from moisture.
- Do not use the caplets after the expiry date printed on the carton or label (EXP.). The expiry date refers to the last day of that month.
- 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 Caplets contain

- The active substance is Paracetamol.
- The other ingredients are: pregelatinised maize starch, sodium metabisulfite (E223) and magnesium stearate.

What Paracetamol Caplets look like and contents of the pack

- The caplets are white, capsule shaped tablets with breakline on one side and plain on the other side.

- They are available in cartons containing 8, 12, 16, 24, 30, 32 or 100 caplets or containers of 16 and 1000 caplets for dispensing purposes.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address:

Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom
Telephone: 0044 (0)1442 200922
E-mail: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Ltd
Laporte Way, Luton, LU4 8WL,
United Kingdom

Manufacturer

Bristol Laboratories Ltd
Unit 5, Traynor Way,
Whitehouse Business Park,
Peterlee, SR8 2RU, United Kingdom

Paracetamol 500 mg Caplets; PL 17907/0001

This leaflet was last revised in January 2025.

To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, fax, email) above.

V17 06-01-25 D0

XXXX