ParaExtra Hard Capsules
Paracetamol 500mg
Caffeine 32mg

Package Leaflet: Information for the user

The full name of this medicine as listed above has been abbreviated throughout the leaflet for ease of reference to 'ParaExtra'.

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 the leaflet or as your doctor or pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4. You must see a doctor if your symptoms worsen or do not improve after 3 days

IN THIS LEAFLET:

1. WHAT PARAEXTRA IS AND WHAT IT IS USED FOR
Each capsule contains paracetamol 500 mg and caffeine 32 mg.
Paracetamol works by relieving pain and reducing high temperatures.
The capsules are for the treatment of the symptoms of mild to moderate pain, such as, **headache, period pains, migraine, rheumatic aches, neuralgia, symptoms of influenza, toothache, feverishness and colds, sore throat, backache, muscle pain.**

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARAEXTRA
Please read the following information.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium free".
Do not take if you:
• are allergic to paracetamol, caffeine or any of the other ingredients of this medicine. (listed in Section 6).
• are under 12 years of age.

Take special care and talk to a pharmacist or your doctor before taking this medicine if you:
• suffer from kidney or liver problems particularly if you have alcoholic liver disease as the hazards of overdose are greater.
• are underweight (weigh less than 50 kg) or are malnourished
• regularly drink alcohol
• are suffering from dehydration
• suffer from a condition called haemolytic anaemia
• suffer from a deficiency of glutathione or glucose-6-phosphate dehydrogenase
• have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), suffer from malnutrition, chronic alcoholism or if you are taking flucloxacillin (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 is taken together with flucloxacillin. Symptoms may include:

serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Contact a doctor immediately if you get a combination of these symptoms.

• consume excessive caffeine (e.g., coffee, tea and some canned drinks). This should be avoided

Do not take with other paracetamol-containing medicines.
You should use the lowest possible dose for the shortest time possible.
Do not exceed the stated dose.

If you are taking other medicines:
Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines;
• if you take blood thinning drugs (anticoagulants e.g. warfarin) 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 Paraextra tablets at the same time as anticoagulants.
• please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see Section 2).
• this product is not recommended if you are taking lithium.

Pregnancy and breast-feeding
Not recommended during pregnancy or breastfeeding, unless recommended by your doctor.

Driving and using machines
Paracetamol is not known to affect driving or using machinery.

3. HOW TO TAKE PARAEXTRA

For oral administration and short term use only.
Dosage: Adults, the elderly and young persons aged 16 and over:
The minimum effective dose should be used for the shortest time necessary to relieve symptoms.
Take 1-2 capsules which may be repeated every four hours, as required. Do not take more than 8 capsules in any 24 hour period.
Adolescents aged 12 to 15 years: 1 capsule which may be repeated every 4 to 6 hours. A maximum of 4 doses in any given 24 hour period.
Not recommended for children under 12 years of age.
If symptoms persist, consult your doctor.
Prolonged use without medical supervision could be harmful.
This product should only be used when clearly necessary and always use the lowest effective dose to relieve your symptoms. Do not take with any other paracetamol-containing products.
If you take more capsules than you should:
If you take too many capsules, **IMMEDIATE** medical advice should be sought even if you feel well, because of the risk of liver damage.

4. POSSIBLE SIDE EFFECTS

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

Stop taking this medicine and tell your doctor immediately if:

Rare (affects between 1 in 1000 people and 1 in 10,000 people)

• You experience allergic reactions such as skin rash, itching, unexpected bruising or bleeding.

Very Rare (affects less than 1 in 10,000 people)

• You experience allergic reactions breathing problems or swelling of the lips, tongue, throat or face.

• Very rare cases of serious skin reactions have been reported.
• You experience a skin rash or peeling, or mouth ulcers.
• You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with this product.
• You experience unexpected bruising or bleeding.
• You experience liver failure.

Other side effects include (whose frequency is not known):
Insomnia, restlessness, anxiety, irritability, headaches, upset stomach, palpitations, nervousness and dizziness.
A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 PARAEXTRA

• Keep out of the sight and reach of children.
• Do not use this medicine 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.
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. CONTENT OF THE PACK AND OTHER INFORMATION

What does this medicine contain?
The active substances are paracetamol and caffeine. Each capsule contains 500 mg of paracetamol and 32 mg of caffeine. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.
The other ingredients are, maize starch, magnesium stearate, sodium laurisulfate, croscarmellose sodium, gelatin, purified water and colours, erythrosine (E127), patent blue V (E131), titanium dioxide (E171) and quinoline yellow (E104), and printing ink: shellac, titanium dioxide (E171), iron oxide, black (E172), propylene glycol, ammonium hydroxide and simeticone.

What your medicine looks like and contents of pack?
The capsules are blue and yellow, imprinted on both sections with "500/32", containing a white, free owing granule mix. ParaExtra is available in pack sizes of 8, 10, 12, or 24 hard capsules. Not all pack sizes may be marketed

Who makes this medicine?
Manufacturer: Haleon Italy Manufacturing S.r.l., Via Nettunense 90, Aprilia, Italy.
Marketing Authorisation Holder: Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland

This leaflet was last revised in May 2025.
PA 678/152/001