

# ParaExtra Hard Capsules

Paracetamol 500 mg  
Caffeine 32 mg

## 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
2. What you need to know before you take ParaExtra
3. How to take ParaExtra
4. Possible side effects
5. How to store ParaExtra
6. Content of the pack and other information

### 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.
- if symptoms persist consult your doctor.
- do not exceed the stated dose.
- immediate medical advice should be sought in the case of overdose.
- do not use this medicine with any other paracetamol-containing products.
- use only when clearly necessary.
- have suffered from serious skin reactions, symptoms of which are skin reddening, blisters or rash.

#### Taking other medicines:

- the absorption of paracetamol is reduced by cholestyramine. Therefore do not take cholestyramine within an hour of taking paracetamol.
- the absorption of paracetamol is increased by metoclopramide and domperidone.
- continual high doses of paracetamol can increase the effects of medicines which thin the blood (e.g. warfarin).
- Paracetamol can increase the absorption of chloramphenicol.

#### Pregnancy and breast-feeding:

If necessary, ParaExtra 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.

Talk to your doctor if you are breastfeeding. If taking ParaExtra for a short period of time as instructed below (see section 3) you can continue to breastfeed. However if you are taking this medicine for a longer period of time or a higher dose as prescribed by a doctor, breastfeeding should be stopped as caffeine passes into breast milk and can cause poor sleep patterns and irritability in infants.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### Driving and using machinery:

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.

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. You can reduce the chances of experiencing side effects by using the minimum dose required. If you experience any of the following serious side effects STOP taking this medicine immediately and contact your Doctor or Pharmacist;

#### Paracetamol

- **Allergic reactions:** Difficulty in breathing, skin rash, swollen facial features or a runny nose.
- **Severe skin reactions:** Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash.
- **Blood:** Rarely the formation of blood clots in the small vessels throughout the body, a severe reduction in the number of white blood cells which makes infections more likely.
- **Other possible side effects:** Include stomach problems such as pain, nausea and vomiting, change in skin colour, bruising, shortness of breath, unusual headaches and unexplained tiredness.

#### Caffeine

- High caffeine intake can result in tremors and palpitations.

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, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@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 laurilsulfate, 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 flowing 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:** Pfizer Consumer Manufacturing Italy S.r.l., Via Nettunense 90, Aprilia, Italy.

**Marketing Authorisation Holder:** GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland.

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