

PACKAGE LEAFLET: INFORMATION FOR THE USE

Paravance Extra Capsules

Paracetamol 500mg

Caffeine 65mg

Read all of this leaflet carefully before you start taking Paravance Extra Capsules because it contains important information for you.

This medicine is available without prescription.

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
- Ask your pharmacist if you need more information or advise
- If you get any side effects, talk to your doctor, pharmacist or nurse. This include any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet?

1. What Paravance Extra Capsules are and what they are used for
2. What you need to know before you take Paravance Extra Capsules
3. How to take Paravance Extra Capsules
4. Possible side effects
5. How to store Paravance Extra Capsules
6. Contents of the pack and other information

1. WHAT PARAVANCE EXTRA CAPSULES ARE AND WHAT THEY ARE USED FOR

Each Paravance Extra Capsule contains paracetamol 500mg and caffeine 65mg. Paracetamol has pain killing (analgesic) and fever reducing (antipyretic) properties. Caffeine is a stimulant for relief of fatigue and drowsiness. Paravance Extra Capsules can be used to treat headache, symptoms of common cold or influenza such as headache, sore throat, body aches and pains, lowering of high temperatures, fatigue and drowsiness.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARAVANCE EXTRA CAPSULES

Do not take Paravance Extra Capsules

- If you are allergic (hypersensitive) to paracetamol or any of the other ingredients listed in section 6
- If you are taking any other paracetamol containing products
- If you have a history of peptic ulcer
- If you are less than 12 years of age

Take special care with Paravance Extra Capsules

- If you have impaired liver or kidney function
- If you are taking other drugs that affect the liver
- If you have a poor diet

Prolonged use, except under medical supervision can be harmful. If symptoms persist contact your doctor or pharmacist. Only take when necessary. Do not exceed the stated dose

Use in children. This product is not to be taken/given to children less than 12 years of age.

Other medicines and Paravance Extra Capsules

Care should be taken while taking this product if you are currently taking:

Anti-emetic drugs such as metoclopramide or domperidone; may increase absorption of paracetamol

Cholesterol drugs such as cholestyramine; may reduce absorption of paracetamol

Anticoagulants such as warfarin; their effect may be enhanced by long term use of paracetamol

Drugs that affect the liver such as monoamine oxidase inhibitors and antidepressants; may increase the hepatotoxicity (liver toxicity) of paracetamol.

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

Taking Paravance Extra Capsules with food and drink

- Alcohol may increase the adverse effects of paracetamol.

Pregnancy, breastfeeding and fertility

Paracetamol is proven to be safe during pregnancy and breast feeding. When taken during pregnancy the half-life of caffeine is prolonged, that is a possible contributing factor in morning sickness. However, as with all medicines, caution should be taken during pregnancy and breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

If necessary, Paravance Extra Capsules 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.

Important information about some of the ingredients of Paravance Extra Capsules

Contains tartrazine, may cause allergic reaction

3. HOW TO TAKE PARAVANCE EXTRA CAPSULES

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

Adults, the elderly and children aged 16 years and over: 2 capsules every 4 hours as required. Do not take more than 8 capsules (4 doses) in 24 hours.

Children: Ages 12 to 15 years: 1 capsule every 4-6 hours when necessary to a maximum of 4 capsules in 24 hours

Do not give to children under 12 years of age.

Elderly population: no dosage adjustment is considered necessary in the elderly.

Do not take this medicine for any longer than a period of 3 days. Please consult a doctor or pharmacist if symptoms persist or worsen, or if the product is required for more than 3 days.

For oral administration. Swallow whole with water, do not chew.

If you take more Paravance Extra Capsules than you should

Immediate medical advice should be sought in the event of an overdose because of the risk of irreversible liver damage. Symptoms of overdose may present as nausea, vomiting, loss of appetite and abdominal pain.

If you forget to take Paravance Extra Capsules

Take the next dose as soon as you remember, if needed. Do not double dose. This product should only be taken when necessary.

If you have any further questions on the use of this medicine as your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paravance Extra Capsules can cause side effects, although not everybody gets them. Side effects may include hypersensitivity reactions such as skin rashes. There have also been reports of blood disorders but these were not necessarily caused by paracetamol

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 HPRC 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 can you help provide more information on the safety of this medicine.

5. HOW TO STORE PARAVANCE EXTRA CAPSULES

Keep out of the sight and reach of children. Do not use Paravance Extra Capsules after the expiry date (EXP Day/Month/Year) which is stated on the carton and blister foil. Do not store above 25°C. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measure will help protect the environment.

6. WHAT PARAVANCE EXTRA CAPSULES LOOK LIKE AND CONTENTS OF THE PACK

What Paravance Extra Capsules contain; each capsules contains 500mg paracetamol and 65mg caffeine as active ingredients. The other ingredients are maize starch, croscarmellose sodium, magnesium stearate, sodium laurilsulfate, gelatin, titanium dioxide, quinolone yellow, erythrosine, patent blue V, shellac, tartarazine (E102) and aluminium hydroxide.

What Paravance Extra Capsules look like and the contents of the pack

Red and yellow hard gelatin capsules printed with “Extra”. Each pack contains a blister tray containing 12 capsules.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd., Dansom lane, Hull, HU8 7DS, UK and Wraftons Laboratories Ltd., Braunton Devon, EX33 2DL, UK.

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For product queries please call (01) 6305429

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