

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Panadol® Extra Tablets
Paracetamol + Caffeine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Outer carton:

Each tablet contains Paracetamol 500 mg and Caffeine 65 mg.

Inner carton:

Active ingredients: Each tablet contains Paracetamol 500 mg and Caffeine 65 mg.

3. LIST OF EXCIPIENTS

Outer carton:

Also contains potassium sorbate (E 202).

Inner carton:

Other ingredients: Starch pregelatinised, maize starch, polyvinyl pyrrolidone, potassium sorbate (E 202), purified talc, stearic acid, croscarmellose sodium, hypromellose and triacetin.

4. PHARMACEUTICAL FORM AND CONTENTS

Outer carton:

Tablet
16

Inner carton:

Packs of Panadol Extra Tablets contain 8, 16 or 32 tablets.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

< see Instructions On Use section below >

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Outer carton:

Please read right through the information on the outside and inside of this pack before you start using this medicine.

If you have any questions, or if there is anything you do not understand, ask your pharmacist.

TAKE SPECIAL CARE

Contains paracetamol. Do not take with any other paracetamol-containing products.

Ask your doctor before you take this medicine:

- if you have **liver** or **kidney disease**, including **alcoholic liver disease**.

Do not take more frequently than every 4 hours.

Do not take more than the recommended dose.

Do not take if you are under 12 years of age.

Avoid too much caffeine in drinks like coffee and tea.

High caffeine intake can cause **difficulty in sleeping, shaking** and an **uncomfortable feeling in the chest**.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If symptoms persist consult your doctor.

Inner carton:

2. CHECK BEFORE YOU TAKE PANADOL EXTRA TABLETS

<X symbol> **Do not take Panadol Extra Tablets:**

- if you have ever had an allergic reaction to paracetamol, caffeine or to any of the other ingredients (listed in Section 4).

<! symbol> If you are taking other medicines
Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]) or **colestyramine** (to lower **blood cholesterol**). 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. But you can still take **occasional** doses of Panadol Extra Tablets at the same time as anticoagulants.

<! symbol> Pregnancy and breast-feeding
Do not take Panadol Extra Tablets if you are **pregnant** or **breast feeding**.

3. POSSIBLE SIDE EFFECTS

Like all medicines, Panadol Extra Tablets can have side effects but not everybody gets them. A small number of people have had side effects. **Stop taking** the medicine and **tell your doctor immediately** if you experience:

- **Allergic reactions** which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- **Skin rash or peeling, or mouth ulcers**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained **bruising** or **bleeding**
- **Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.**

If you do get any side effects, even those not mentioned in this information, tell your doctor or pharmacist.

If your symptoms continue or your headache becomes persistent, **see your doctor.**

8. EXPIRY DATE

DO NOT USE AFTER THE EXP DATE:

9. SPECIAL STORAGE CONDITIONS

Store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

< not applicable >

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Outer carton:

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

<Company logo>

Inner carton

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is GlaxoSmithKline Dungarvan Ltd., Co. Waterford, Ireland.

Panadol and the **Roundel device** are registered trade marks owned by or licensed to the GSK group of companies

<Company logo>

12. MARKETING AUTHORISATION NUMBER(S)

PL 44673/0087

13. BATCH NUMBER

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

< not applicable – GSL >

15. INSTRUCTIONS ON USE

Outer carton:

- ✓ Backache
- ✓ Muscular aches
- ✓ Migraine headache
- ✓ Easy on the stomach

Panadol Extra Tablets provide extra effective pain relief.

- headache
- toothache
- backache
- migraine
- sore throat
- period pain
- helps reduce temperature
- aches and pains of colds and flu
- rheumatic pain
- fever

HOW TO TAKE

Adults and children 16 years and over:

Swallow 2 tablets every 4 hours as needed. Do not take more than 8 tablets in 24 hours.

Children aged 12-15 years:

Swallow 1 tablet every four hours as needed. Do not give more than 4 tablets in 24 hours.

Inner carton

4. WHAT PANADOL EXTRA TABLETS DO

Panadol Extra Tablets are used for the relief of headache, migraine, backache, rheumatic pain, toothache and period pain. They also relieve sore throat and the fever, aches and pains of colds and flu.

The tablets contain two active ingredients. Paracetamol is a painkiller and also reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

This information was last revised in September 2016.

16. INFORMATION IN BRAILLE

panadol extra tablets

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3. LIST OF EXCIPIENTS

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4. PHARMACEUTICAL FORM AND CONTENTS

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15. INSTRUCTIONS ON USE

< not applicable >

16. INFORMATION IN BRAILLE

< *not applicable* >