

GSK - TEMPLATE NO. 5 (front)
Dimensions : 210mm x 150 mm version 2

LEADING EDGE

BLANK MARGINS:

Top: 8.2mm
Bottom: 5.8mm
Left: 12mm
Right: 12mm

PHARMACODE:
No pharmacode on
front panel.

210mm



500mg/65mg Soluble Effervescent Tablets Paracetamol/Caffeine

PATIENT INFORMATION LEAFLET

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Panadol Extra Soluble tablets carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Panadol Extra Soluble tablets do
- Check before you take Panadol Extra Soluble tablets
- How to take Panadol Extra Soluble tablets
- Possible side effects
- How to store Panadol Extra Soluble tablets
- Further information

1. What Panadol Extra Soluble tablets do

Panadol Extra Soluble tablets are used for the relief of headache, migraine, backache, rheumatic pain, muscle pain, toothache and period pain. They also relieve discomfort in colds, flu and sore throat and help reduce temperature.

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

2. Check before you take Panadol Extra Soluble tablets

X Do not take Panadol Extra Soluble tablets:

- if you have ever had an allergic reaction to paracetamol, caffeine or to any of the other ingredients (listed in Section 6).
- if you are taking other medicines containing paracetamol.
- If you are under 12 years.

! Ask your doctor before you take this medicine:

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

! 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 (for nausea [feeling sick] or vomiting [being sick]) or chloramphenicol (used to treat infections) or cholestyramine (for high 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 Soluble tablets at the same time as anticoagulants.

! Taking Panadol Extra Soluble with food and drink:

- Panadol Extra Soluble contains 65mg of caffeine per tablet, therefore avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.

! Pregnancy and breastfeeding

Not recommended for use during pregnancy. Use during breastfeeding should be avoided.

! Important information about some of the ingredients of Panadol Extra Soluble tablets

Panadol Extra Soluble contains 427mg sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

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Eye mark 8mm high x 2mm wide, Front panel only RHS of web, centred in a clear margin. Centre of eye mark to be 83.6mm from leading edge. There must be a 2mm gap between the text and the eyemark and eyemark must be 2mm from edge.

83.6mm

TRAILING EDGE

150mm

GSK - TEMPLATE NO. 5 (back)
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3. How to take Panadol Extra Soluble tablets

Panadol Extra Soluble tablets should be dissolved in at least half a tumbler of water.

✓ Adults, elderly and children aged 12 years and over:

Take 2 tablets, up to 4 times daily as required.

Children under 12 years:

Do not give to children under 12 years.

- ! Do not take more frequently than every 4 hours.**
- Do not take more than 8 tablets in 24 hours.
 - Do not exceed the stated dose.
 - This product should be used only when clearly necessary.
 - If symptoms persist consult your doctor.
 - Prolonged use except under medical supervision may be harmful.
 - If your symptoms continue or your headache becomes persistent, see your doctor.

If you take too many tablets

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.

4. Possible side effects

Like all medicines, Panadol Extra Soluble tablets can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor immediately if:

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

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- 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 changes in blood tests that measure the function of your liver.

Other side effects include: insomnia, restlessness, anxiety, irritability, headaches,

upset stomach, palpitations, nervousness and dizziness.

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

5. How to store Panadol Extra Soluble tablets

Keep out of the reach and sight of children. Do not store above 25°C.

Do not use this medicine after the expiry date (EXP) shown on the carton and blisters. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Panadol Extra Soluble Effervescent Tablets.

Flat, white tablets with bevelled edges, plain on one side, breakline on the other. The tablet can be divided into equal halves.

Active ingredient Each tablet contains Paracetamol 500mg and Caffeine 65mg.

Other ingredients Sorbitol, saccharin sodium, sodium hydrogen carbonate, povidone, sodium laurilsulfate, dimeticone, citric acid (anhydrous) and sodium carbonate (anhydrous).

Packs of Panadol Extra Soluble contains 12 or 24 tablets in blister strips. Not all pack sizes may be marketed.

The Product Authorisation holder is GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 and all enquires should be sent to this address.

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

This leaflet was last revised in August 2011.

Panadol is a registered trade mark of the GlaxoSmithKline group of companies.

PA 678/39/10

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PHARMACODE:
Code 8mm high. On back, code on LHS of web, last bar to be 30mm from trailing edge. First bar to be nearest to leading edge. Reading from right to left. Code must be 2mm from text and 2mm from edge.

Right bar

Left bar

30mm

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 Process Black				<table><tr><td>Project Name</td><td>ULT + GDS + Beacon</td></tr><tr><td>Brand</td><td>Panadol</td></tr><tr><td>Variant</td><td>Extra Soluble Tabs</td></tr><tr><td>Component</td><td>PIL</td></tr><tr><td>Country</td><td>Ireland</td></tr><tr><td>Drawing No.</td><td>GSK TEMPLATE 5</td></tr><tr><td>Dimensions</td><td>210 x 150mm</td></tr><tr><td>Factory Code</td><td>-</td></tr><tr><td>SKU Code</td><td>-</td></tr><tr><td>Pharma Code</td><td>-</td></tr><tr><td>Datamatrix Code</td><td>-</td></tr><tr><td>Barcode No.</td><td>-</td></tr><tr><td>Mag & Bwr</td><td>-</td></tr><tr><td>Printer</td><td>Pharmagraphics Guy LTD</td></tr><tr><td>Print Process</td><td>-</td></tr><tr><td>No. of Colours</td><td>1 (One)</td></tr><tr><td>Substrate</td><td>60gsm</td></tr><tr><td>Date</td><td>09th August 2011</td></tr><tr><td>Brand Manager</td><td>Nuala Beecher</td></tr></table>		Project Name	ULT + GDS + Beacon	Brand	Panadol	Variant	Extra Soluble Tabs	Component	PIL	Country	Ireland	Drawing No.	GSK TEMPLATE 5	Dimensions	210 x 150mm	Factory Code	-	SKU Code	-	Pharma Code	-	Datamatrix Code	-	Barcode No.	-	Mag & Bwr	-	Printer	Pharmagraphics Guy LTD	Print Process	-	No. of Colours	1 (One)	Substrate	60gsm	Date	09th August 2011	Brand Manager	Nuala Beecher
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