6. Further information

Panadol Extra tablets are white to off white oval shaped coated tablets debossed "xPx" with P inside a circle on one side.

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

Other ingredients Starch pregelatinised, Povidone K-25, Calcium carbonate, Crospovidone, Sodium methyl parahydroxybenzoate (E219), Sodium ethyl parahydroxybenzoate (E215), Sodium propyl parahydroxybenzoate (E217), Alginic Acid and Magnesium stearate.

Film coat Titanium dioxide, Hypromellose, Macrogol and Polysorbate 80.

Polishing agent Carnauba wax.

Packs of Panadol Extra tablets contain 4, 6, 12, 24, 30, 48, 60 and 96 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 2012.

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

PA 678/27/1

TRAILING EDGE



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Film-coated tablets Paracetamol 500mg **Caffeine 65mg**

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 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:

- 1. What Panadol Extra tablets do
- 2. Check before you take Panadol Extra tablets
- 3. How to take Panadol Extra tablets
- 4. Possible side effects
- 5. How to store Panadol Extra tablets
- 6. Further information

1. What Panadol Extra tablets do

Panadol Extra tablets are used for the relief of headache, migraine, backache, rheumatic pain, muscle pain, neuralgia, 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 tablets**



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 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 severe 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 or domperidone (for nausea [feeling sick] or vomiting [being sick]) 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 tablets at the same time as anticoagulants.



Important information about some of the ingredients

Contains parahydroxybenzoates which may cause allergic reaction (possibly delayed).



Pregnancy and breastfeeding

Not recommended during pregnancy, unless recommended by your doctor.

Use during breastfeeding should be avoided.

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2mm from edge

Adults, elderly and children aged 12 years and over:

3. How to take Panadol Extra tablets

Swallow 2 tablets with water up to 4 times daily as needed.



- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets in 24 hours.
- Do not take more than the recommended dose.
- If symptoms persist consult your doctor.
- Prolonged use except under medical supervision may be harmful.
- · Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficultly sleeping, shaking and an uncomfortable feeling in the chest.

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 tablets can have side effects, but not everybody gets them.

Stop taking the medicine and tell your doctor if you experience:

- · allergic reactions such as skin rash, or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- or have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product.
- severe rash, peeling of the skin which may be accompanied by mouth ulcers.

These reactions are rare.

The following side effects may also occur. **Tell your doctor** if you get them.

• In all the years paracetamol has been used there have been very rare reports of blood disorders, but these were not necessarily caused by paracetamol. These effects should go away once you stop taking the medicine.

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