

Panadol Ultra

PL 44673/0010

Leaflet

<Panadol logo>

Panadol Ultra

Paracetamol + Codeine

[Exclamation symbol]

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked.
- You should only take this product for a **maximum of 3 days** at a time. If you need to take it for longer than 3 days you should **see your doctor or pharmacist** for advice.
- This medicine **contains codeine** which can **cause addiction** if you take it continuously for **more than 3 days**. This can give you **withdrawal symptoms** from the medicine when you stop taking it.
- If you take this medicine for headaches for **more than 3 days** it can **make them worse**.

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 Ultra tablets carefully to get the best results from them.

- Keep this leaflet you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Panadol Ultra does
2. Check before you take Panadol Ultra
3. How to take Panadol Ultra
4. Possible side effects
5. How to store Panadol Ultra
6. Further information

1. What Panadol Ultra does

Panadol Ultra tablets are for the **short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone**. They can be used for migraine, headache, dental pain, period pain, strains & sprains, backache, arthritic & rheumatic pain and sciatica. The tablets contain two active ingredients. Paracetamol and codeine are painkillers. By working on your body in different ways, they combine to relieve pain.

Codeine can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

2. Check before you take Panadol Ultra

- This medicine **contains codeine** which can **cause addiction** if you take it continuously for **more than 3 days**. This can give you **withdrawal symptoms** from the medicine when you stop taking it.

- If you take a painkiller for headaches for **more than 3 days** it can **make them worse**.

[Cross symbol] **Do not take Panadol Ultra:**

- **If you have ever had an allergic reaction** to paracetamol, codeine, other opioid painkillers or to any of the other ingredients (listed in Section 6)
- If you are **taking other medicines containing paracetamol or codeine**
- If you are **breast-feeding**.

[Exclamation symbol] **Ask your doctor before you take this medicine:**

- If you have **liver or kidney disease**, including **alcoholic liver disease**
- If you have **bowel problems** including blockage of your bowel
- If you have had an **operation to remove your gall bladder**
- If you have been told by your doctor that you have an **intolerance to some sugars**.

[Exclamation symbol] **Warnings and Precautions**

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

[Exclamation symbol] **Driving and operating machinery**

This medicine can affect your ability to drive as it may make you sleepy or dizzy. **Do not drive** while taking this medicine until you know how it affects you.

- It may be offence to drive when taking this medicine.
- However, you would not be committing an offence if the medicine has been taken to treat a medical or dental problem, and you have taken it according to the information provided with the medicine and it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine. Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: www.gov.uk/drug-driving-law.

[Exclamation 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]); **colestyramine** (to lower **blood cholesterol**); **monoamine oxidase inhibitors** (MAOIs prescribed for **depression**) or medicines that make you **drowsy**. 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 Ultra at the same time as anticoagulants.

[Exclamation symbol] **Children and adolescents**

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

[Exclamation symbol] **Pregnancy and breast feeding**

Talk to your **doctor** before taking Panadol Ultra if you are **pregnant**. **Do not use whilst breast-feeding.**

3. How to take Panadol Ultra

[Tick symbol]

Adults aged 18 years and over:

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

Children aged 16 to 17 years:

Swallow 2 tablets every 6 hours as needed. Do not take more frequently than **every 6 hours**. Do not take more than **8 tablets in 24 hours**.

Children aged 12 to 15 years:

Swallow 1 tablet every 6 hours as needed. Do not take more frequently than **every 6 hours**. Do not take more than 4 tablets in 24 hours.

[Exclamation symbol]

- Do not take **more than the recommended dose**.
- Do not give to children **under 12 years**.
- Do not take for more than **3 days**. If you need to use this medicine for more than **3 days** you **must speak** to your doctor or pharmacist.

Possible withdrawal effects

This medicine **contains codeine** and can **cause addiction** if you take it continuously for **more than 3 days**. When you stop taking it you may get **withdrawal symptoms**. You should **talk to your doctor or pharmacist** if you think you are suffering from withdrawal symptoms.

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.

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

4. Possible side effects

Some people may have side effects when using this medicine. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

When using this product you may experience:

- Constipation.

Stop taking this medicine and **tell your doctor immediately** if you experience:

- Severe **abdominal pain, nausea** and **vomiting** if you have recently had your gall bladder removed
- **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**
- Confusion
- Sleepiness
- Small pupils
- **Nausea, vomiting, sudden weight loss, loss of appetite and yellowing of the eyes and skin.**

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

[Exclamation symbol] **How do I know if I am addicted?**

If you take this medicine according to the instructions on the pack, it is unlikely you will become addicted to the medicine. However, if the following apply to you it is important that you **talk to your doctor**:

- You need to take the medicine for **longer periods of time**.
- You need to take **more than the recommended dose**.
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again.

5. How to store Panadol Ultra

Keep out of the sight and reach of children.

Do not use this medicine after the 'EXP' date shown on the pack.

6. Further information

Active ingredients: Each tablet contains Paracetamol 500 mg and Codeine Phosphate Hemihydrate 12.8 mg.

Other ingredients: Starch pregelatinised, povidone, potassium sorbate (E 202), maize starch, talc, magnesium stearate, stearic acid, microcrystalline cellulose, croscarmellose sodium, Opadry II Pink 31F24615 (containing lactose monohydrate, hypromellose, macrogol, quinoline yellow (E 104), erythrosine (E 127) and titanium dioxide (E 171)).

Packs of Panadol Ultra contain 20 tablets.

The **marketing authorisation holder** is Haleon UK Trading Limited, Weybridge, KT13 ONY, U.K. and all enquiries should be sent to this address.

The **manufacturer** is SmithKline Beecham S.A. Carretera de Ajalvir, Km 2,500, Alcala de Henares, 28806 Madrid, Spain.

This leaflet was last revised in May 2023.

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