

Solpadeine[®] PLUS CAPSULES

Paracetamol, Codeine,
Caffeine

- 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 Solpadeine Plus Capsules 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 Solpadeine Plus Capsules do
2. Check before you take Solpadeine Plus Capsules
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1. What Solpadeine Plus Capsules do

Solpadeine Plus Capsules can be used in patients **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. They can be used for migraine, headache, dental pain, period pain, strains & sprains, backache, rheumatic pain and sciatica. The capsules contain three active ingredients; paracetamol, codeine and caffeine. Codeine and paracetamol are both painkillers. 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 painkillers. Caffeine acts to further help the effectiveness of paracetamol.

2. Check before you take Solpadeine Plus Capsules

- 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.

Do not take Solpadeine Plus Capsules:

- If you have ever had an allergic reaction to paracetamol, caffeine, 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 under 12 years:

- For pain relief in children and adolescents (0-18 years of age) after **removal of their tonsils or adenoids** due to **obstructive sleep apnoea syndrome**
- If you know that you **metabolise very rapidly codeine into morphine**

If you are **breastfeeding**.

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 are taking other medicines

Talk to your doctor or pharmacist before taking these capsules 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 in the last 2 weeks or substances that make you **drowsy** (e.g. sedatives, antidepressants or alcohol). 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 Solpadeine Plus Capsules at the same time as anticoagulants.

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.

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.

Pregnancy and breast feeding

Talk to your doctor before taking Solpadeine Plus Capsules if you are **pregnant**. **Do not take** Solpadeine Plus Capsules while you are **breast-feeding**. Codeine and morphine passes into breast milk.

Driving and using machines

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 is an **offence** to drive if this medicine affects your ability to drive.

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

3. How to take Solpadeine Plus Capsules

Adults and children aged 12 years and over:

Swallow 2 capsules every 4 hours as needed.

- Do not take more frequently than **every 4 hours**
- Do not take more than **8 capsules in 24 hours**
- Do not take **more than the recommended dose**
- **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**
- Solpadeine Plus Capsules should not be taken by children **below the age of 12 years**, due to the risk of severe breathing problems
- This medicine should not be taken for more than **3 days**. If the pain does not improve after 3 days, **talk to your doctor** for advice.

Possible withdrawal effect

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.

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause 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, dry mouth, nausea and

vomiting if you have recently had your gall bladder removed

- Nervousness, dizziness, irritability, drowsiness or restlessness
- **Allergic reactions** which may be severe such as skin rash and itching
- **Skin rash or peeling or mouth ulcers; itching or sweating**
- **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, upset stomach, sudden weight loss, loss of appetite and yellowing of the eyes and skin**
- Difficulty urinating.

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 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.

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 Solpadeine Plus Capsules

Keep out of the reach and sight of children.

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

Store below 25°C.

6. Further information

Active ingredients Each capsule contains Paracetamol 500 mg, Codeine Phosphate Hemihydrate 8 mg and Caffeine 30 mg.

Other ingredients Maize starch, magnesium stearate, titanium dioxide (E 171), erythrosine (E 127), patent blue V (E 131), quinoline yellow (E 104), gelatin, shellac, propylene glycol (E 1520), iron oxide black (E 172) and ammonium hydroxide (E 527).

Packs of Solpadeine Plus Capsules contain 16 or 32 capsules, they have an opaque red cap and opaque white body, with "solpadeine" printed in black on both halves or plain on both halves.

The marketing authorisation holder is Omega Pharma Ltd., 32 Vauxhall Bridge Road, London, SW1V 2SA, United Kingdom and all enquiries should be sent to this address.

The manufacturer is SmithKline Beecham S.A., Carretera de Ajalvir, Km 2500, 28806 Alcala De Henares, Madrid, Spain or Swiss Caps GmbH Grassingerstraße 9 83043 Bad Aibling, Germany (Aenova Group).