



FRONT PAGE

LEADING EDGE

8.2mm
75mm
105mm
RIGHT HAND BAR
LEFT HAND BAR
5.8mm
PHARMACODE: Code 8mm high. Code on same edge as front, right hand bar to be 75mm from leading edge and leads into the machine.
There is to be a 2mm clear (print free) gap between pharmacode and text.

Solpadeine PLUS TABLETS
Paracetamol, Caffeine

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked.
- You should only take this medicine 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 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 Solpadeine Plus Tablets do
2. Check before you take Solpadeine Plus Tablets
3. How to take Solpadeine Plus Tablets
4. Possible side effects
5. How to store Solpadeine Plus Tablets
6. Further information

1. What Solpadeine Plus Tablets do
Solpadeine Plus Tablets 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, backache and rheumatic pain. The tablets 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 Tablets
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.

Do not take Solpadeine Plus Tablets:

- 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 tablets if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea (feeling sick) and 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 Tablets 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.

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TRAILING EDGE
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BACK PAGE

LEADING EDGE

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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 Tablets if you are pregnant. Do not take Solpadeine Plus Tablets while you are breastfeeding. Codeine and morphine passes into breast milk.

3. How to take Solpadeine Plus Tablets

- Adults and children aged 12 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.
- 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 Tablets 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 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.

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 sometimes with swelling of the mouth or face or shortness of breath
- 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 in 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 Tablets
Keep out of the reach and sight 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, Codeine Phosphate Hemihydrate 8 mg and Caffeine 30 mg.
Other ingredients Maize starch, starch pregelatinised, potassium sorbate (E 202), povidone, purified talc, magnesium stearate, microcrystalline cellulose, stearic acid, hypromellose and carmoisine (E 122).
Carmoisine may cause allergic reactions.
Packs of Solpadeine Plus Tablets contain 16 or 32 tablets.

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 GlaxoSmithKline Dungarvan Ltd., Co. Waterford, Ireland or Omega Pharma Manufacturing GmbH & Co. KG, Benzstraße 25, 71083 Herrenberg, Germany.
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TRAILING EDGE
140mm
12mm

100 mm
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Eye mark 8mm high x 2mm wide. Front panel only RHS of web, centred in a clear margin. Top of eye mark to be 64.2mm from leading edge.
There is to be a 2mm clear (print free) gap between eye mark and text.

Regulatory Approval:

Sign:..... Date:.....

Name (please print):.....

Contact email:.....

Marketing Approval:

Sign:.....

Name (please print):.....

Contact email:.....

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