

↑ Into Machine ↑

FRONT PAGE

LEADING EDGE

8.2mm

75mm

105mm

RIGHT HAND BAR

LEFT HAND BAR

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.

5.8mm

64.2mm

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.

Solpadeine PLUS
TABLETS
Paracetamol, Codeine, Caffeine

1. What Solpadeine Plus Tablets do
Solpadeine Plus 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, backache and rheumatic pain. The tablets contain three active ingredients, Paracetamol and codeine are painkillers. By working on your body in different ways, they combine to relieve pain. 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.
- If you take a painkiller for headaches for more than 3 days it can make them worse.

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.

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

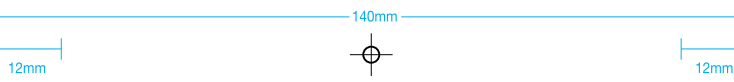
Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines, particularly metoprolol or domperidone (for nausea/feeling sick) and vomiting (being sick); colestyramine (to lower blood cholesterol); monoamine oxidase inhibitors (MAOIs) prescribed for depression in the last 2 weeks or substances that make you drowsy (eg, 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.

Pregnancy and breast feeding

Talk to your doctor before taking Solpadeine Plus Tablets if you are pregnant. Do not use whilst breast feeding unless advised by your doctor.

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TRAILING EDGE



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BACK PAGE

LEADING EDGE

8.2mm

105mm

RIGHT HAND BAR

LEFT HAND BAR

PHARMACODE: Code 8mm high. Code on same edge as front, right hand bar to be 25mm from leading edge and leads into the machine.

There is to be a 2mm clear (print free) gap between pharmacode and text.

25mm

5.8mm

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.
- 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. Also you can help make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard, alternatively you can call freephone 0800 100 3332 (available between 10am-2pm Monday-Friday) or fill in a paper form available from your local pharmacy.

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

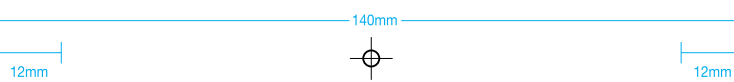
5. How to store Solpadeine Plus Tablets
Keep out of the reach and sight of children. Do not use this medicine after the 'EXP' date shown on the pack.

6. Further information
Active ingredients: Each tablet contains Paracetamol 500 mg, Codeine Phosphate Hemihydrate 8 mg and Caffeine 30 mg.
Other ingredients: Maltose starch, starch pregelatinised, potassium sorbate (E 202), povidone, purified talc, magnesium stearate, microcrystalline cellulose, stearic acid, hydroxypropylcellulose 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 Dungenan Ltd., Co. Waterford, Ireland or GlaxoSmithKline GmbH & Co. KG, Benzstraße 25, 71083 Herrenberg, Germany.
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