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Do not take Solpadeine Max Tablets:

- 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
- 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 have been told by your doctor that you have an intolerance to some sugars.

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 Solpadeine Max 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.

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.

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Pregnancy and breast feeding
Talk to your doctor before taking Solpadeine Max Tablets if you are pregnant. Do not take Solpadeine Max Tablets 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 Max Tablets
Adults:
Swallow 2 tablets every 4-6 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 – 18 years:
Swallow 1-2 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 – 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.

- Do not take more than the recommended dose.
- Solpadeine Max 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, 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 serious skin reactions (very rare cases reported)
- 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, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

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 Max 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 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, lactose monohydrate, hypromellose, macrogol, quinoline yellow (E 104), erythrosine (E 127) and titanium dioxide (E 171).
Packs of Solpadeine Max Tablets contain 20 or 30 tablets with MAX embossed one side or plain on both sides.
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 Omega Pharma Manufacturing GmbH & Co. KG, Benzstraße 25, 71083, Herrenberg, Germany or SmithKline Beecham S.A. Carretera de Ajalvir Km 2500, Alcalá de Henares, 28806 Madrid, Spain or Swiss Caps GmbH Grassingerstraße 9, 83043 Bad Aibling, Germany (Aenova Group).
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First Bar
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