

Solpadeine[®] MAX SOLUBLE TABLETS

Paracetamol, Codeine,
Caffeine

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked.
- This medicine has been provided to you and should not be given to anyone else.
- 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 Max Soluble 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.

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1. What Solpadeine Max Soluble Tablets do

Solpadeine Max Soluble 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, dental pain, strains & sprains, backache, arthritic & rheumatic pain and sciatica. The tablets contain three active ingredients; paracetamol, codeine and caffeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Paracetamol is another analgesic to relieve pain. Caffeine acts to further help the effectiveness of paracetamol.

2. Check before you take Solpadeine Max Soluble 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.
- This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.
- If you take a painkiller for headaches for more than 3 days it can make them worse.

Do not take Solpadeine Max Soluble Tablets:

- If you have ever had an allergic reaction to paracetamol, codeine, caffeine or to any of the other ingredients (listed in Section 6)
- If you are taking other medicines containing paracetamol.
- 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 pregnant or breastfeeding.
- If you have respiratory depression or chronic constipation.

Ask your doctor before you take this medicine:

- If you have been told by your doctor that you have an intolerance to some sugars
- If you are on a controlled sodium diet

Each tablet contains 427 mg of sodium. This is equivalent to 22% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you take this medicine daily for a prolonged period or repeatedly for two days every week, especially if you have been advised to follow a low salt (sodium) diet.

This medicine contains 50mg sorbitol (E420) per tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or

your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

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]); cholestyramine (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) or sedated (e.g. benzodiazepines or related medicines). 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 Soluble Tablets at the same time as anticoagulants. If you take medicine to treat gout and hyperuricemia (e.g. probenecid), flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used. Pregabalin and gabapentin as there is an increased risk of respiratory depression.

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 on a controlled sodium diet.
- If you have hypotension or hypothyroidism
- If you have experienced a recent head injury or raised intracranial pressure.
- If you have asthma and have been told by your doctor that you are sensitive to aspirin.
- If you have Gilbert's Syndrome (familial non-haemolytic jaundice)
- If you are taking other medicines that can affect liver function
- If you have glucose-6-phosphatase dehydrogenase deficiency
- If you have haemolytic anaemia
- If you have glutathione deficiency
- If you are dehydrated
- If you have a poor diet such that the diet causes health problems
- If you weigh less than 50kg
- If you are elderly
- If you have a condition called myasthenia gravis which weakens the muscles. They may reduce your dose or increase the time interval between doses of your medicine.

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.

Talk to your doctor or pharmacist before taking Solpadeine Max Soluble Tablets:

- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you feel you need to take more of Solpadeine Max Soluble Tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Taking higher doses or more frequent doses of opioids, such as codeine (an active ingredient of this medicine), may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor or pharmacist about your treatment. Please refer Section 3 'How to take Solpadeine Max Soluble Tablets' for information on correct dosages and time intervals.

Do not take this medicine continuously for longer than 3 days.

Possible withdrawal effect:

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. If you become addicted, when

you stop taking it you may get withdrawal symptoms. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling of being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. You should talk to your doctor if you think you are suffering from withdrawal symptoms.

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

Do not take Solpadeine Max Soluble Tablets if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Solpadeine Max Soluble Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Solpadeine Max Soluble Tablets while you are breast-feeding. Codeine and morphine passes into breast milk and will affect your baby.

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 Soluble Tablets

Adults:

Take 2 tablets dissolved in a full tumbler of water (200ml), 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.

A reduced maximum daily dose should be considered if you are underweight (under 50kg)

For the elderly a reduced dose may be required.

Adolescents aged 16 – 18 years:

Take 1-2 tablets dissolved in a full tumbler of water (200ml), every 6 hours as needed.

- Do not take more frequently than every 6 hours.
- Do not take more than 8 tablets in 24 hours.

Adolescents aged 12 – 15 years:

Take 1 tablet dissolved in a full tumbler of water (200ml), 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.
- 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 Max Soluble 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.

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
- Nervousness, dizziness, irritability, drowsiness or restlessness
- 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
- Cloudy urine or difficulties 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 you notice any of the following signs 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
- You are using the medicine for reasons other than instructed.
- 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 Soluble Tablets

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. Protect from light and moisture

6. Further information

Active ingredients Each effervescent tablet contains Paracetamol 500 mg, Codeine Phosphate Hemihydrate 12.8 mg and Caffeine 30 mg.

Other ingredients Sorbitol (E 420), sodium saccharin, sodium bicarbonate, sodium lauryl sulfate, citric acid, sodium carbonate, polyvidone and dimeticone

Packs of Solpadeine Max Soluble Tablets contain 24 effervescent tablets.

The marketing authorisation holder is Omega Pharma Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom and all enquiries should be sent to this address.

The manufacturer is GlaxoSmithKline Dunganvar Ltd., Co. Waterford, Ireland or Swiss Caps GmbH Grassingerstraße 9, 83043 Bad Aibling, Germany (Aenova Group).

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