Package leaflet: Information for the user

Solpadeine MAX SOLUBLE TABLETS

Paracetamol, Codeine, Caffeine

- This medicine can only be used for the short term treatment of acute moderate pain when other pain-relieving medicines have not worked. It is recommended for the relief of headache, migraine, dental pain, period pain, strains & sprains, backache, arthritic & rheumatic pain and sciatica.
- 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**.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Solpadeine Max Soluble Tablets are and what they are used for
2. What you need to know before you take Solpadeine Max Soluble Tablets
3. How to take Solpadeine Max Soluble Tablets
4. Possible side effects
5. How to store Solpadeine Max Soluble Tablets
6. Contents of the pack and other information

1. What Solpadeine Max Soluble Tablets are and what they are used for

Solpadeine Max Soluble Tablets contain the active substances paracetamol 500 mg and codeine phosphate hemihydrate 12.8 mg , which are both pain-relieving drugs, and caffeine 30 mg, a stimulant which acts to enhance the pain-relieving effects of paracetamol.
Solpadeine Max Soluble Tablets can be used in patients **over 12 years** of age for the **short-term relief of acute moderate pain that is not relieved by other pain-relieving medicines** such as paracetamol or ibuprofen alone. They can be used for migraine, headache, dental pain, period pain, strains & sprains, backache, arthritic & rheumatic pain and sciatica.

2. What you need to know 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 pain-reliever for headaches for **more than 3 days,** it can **make them worse**.

Do not take Solpadeine Max Soluble Tablets:

- **If you are allergic** to paracetamol, codeine, caffeine, other opioid pain-relieving medicines or to any of the other ingredients of this medicine (listed in Section 6).
- 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 (breathing difficulties)** or **chronic constipation.**

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 and inflammation of your bowel
- If you have had an **operation to remove your gall bladder**
- If you have **hypotension** (low blood pressure) or **hypothyroidism** (an underactive thyroid gland with tiredness, weight gain, and skin and hair changes)
- 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** (abnormal breakdown of red blood cells, which may cause weakness or pale skin)
- 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 **have an enlarged prostate**
- If you are **alcohol dependent**
- If you are **elderly**
- If you have a condition called **myasthenia gravis** which weakens the muscles
- If you are taking **other medicines that make you sleepy or relax your muscles** (such as sleeping tablets or sedatives, gabapentin, pregabalin)
- If you have **Addison's disease**, a condition where your adrenal glands do not produce enough of the hormones your body need

If you are taken or have taking within the preceding two weeks, monoamine oxidase inhibitors (MAOIs) (antidepressants) you should not use this product.

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Solpadeine Max Soluble Tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Solpadeine Max Soluble Tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Solpadeine Max Soluble Tablets, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'

- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Solpadeine Max Soluble Tablets).

During treatment with Solpadeine Max Soluble Tablets, tell your doctor straight away if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Solpadeine Max Soluble Tablets:
• You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Sleep-related breathing disorders
Solpadeine Plus Tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

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.**

Prolonged use of any type of pain-reliever for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of medication overuse headache should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Do not exceed the stated dose.

If symptoms persist for more than 3 days or get worse, or if any other symptoms occur, treatment should be discontinued, and a physician consulted.

Do not take other paracetamol or codeine-containing products concurrently. Immediately contact your doctor in case of overdose, even if you feel well because of the risk of irreversible liver damage.

Liver damage can happen if paracetamol is taken for a long time or in higher doses than recommended. This risk is greater with medicines that contain both paracetamol and codeine, because some people may start taking them too often due to becoming dependent on the codeine part (see warnings above).

Children and adolescents:
Use in adolescents **after surgery**:
Codeine should not be used for pain relief in adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in adolescents with **breathing problems**:
Codeine is not recommended in adolescents with breathing problems since the symptoms of morphine toxicity may be worse in these adolescents.

Do not give to children under the age of 12 years.

Other medicines and Solpadeine Max Soluble Tablets:
Talk to your doctor or pharmacist before taking these soluble tablets if you are taking, have recently taken or might take any other 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;
- **Gabapentin** or **pregabalin** to treat **epilepsy** or **pain due to nerve problems (neuropathic pain);**
- Substances that make you **drowsy** (e.g. sedatives, tranquilizers, antidepressants or alcohol) **or sedated** (e.g. **benzodiazepines** or related medicines).
- **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.
- medicine to treat **gout and hyperuricemia** (e.g. **probenecid**);
- other **medicines that can affect your liver** (e.g. **barbiturates such as phenobarbitone, tricyclic antidepressants, alcohol, carbamazepine, phenytoin, primidone, rifampicin, St John's Wort**);
- **chloramphenicol**, an **antibiotic**;
- **anaesthetics**, **hypnotics**, **phenothiazines;**
- **decongestants** (to unblock your nose).

Please inform your doctor or pharmacist if you are taking:
Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Concomitant use of Solpadeine Max Soluble Tablets and medicines with sedative effects such as benzodiazepines or related drugs, gabapentinoids (gabapentin and pregabalin) increases the risk of drowsiness, difficulties in breathing (respiratory depression), low blood pressure, coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Solpadeine Max Soluble Tablets together with medicines with sedative effects the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Taking this medicine with food and drink
Do not drink alcohol while taking this product.
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**.

Pregnancy and breast feeding:
Do not take Solpadeine Max Soluble Tablets if you are pregnant or think you might be pregnant.

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

The 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 prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in 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.

Further information on the UK drug-driving law is available at www.gov.uk/drug-driving-law

Solpadeine Max Soluble Tablets contain sodium. 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 need to 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.

Solpadeine Max Soluble Tablets contain sorbitol. 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.

3. How to take Solpadeine Max Soluble Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Take 2 tablets dissolved in a full tumbler of water (200ml), every 4-6 hours as needed up to 4 times a day.
Do not take more frequently than every 4 hours.
Do not take more than 4 doses (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.
Patients with kidney or liver disease must seek medical advice before taking this medicine.

Adolescents aged 16 – 18 years:

Take 1-2 tablets dissolved in a full tumbler of water (200ml), every 6 hours as needed up to 4 times a day.
Do not take more frequently than every 6 hours.
Do not take more than 4 doses (8 tablets) in 24 hours.

Adolescents 12 – 15 years:

Take 1 tablet dissolved in a full tumbler of water (200ml), every 6 hours as needed up to 4 times a day.
Do not take more frequently than every 6 hours.
Do not take more than 4 doses (4 tablets) in 24 hours.

- Do not take **more medicine than the label tells you to.**
- **Do not exceed the recommended daily dosage or the specified number of doses because of the risk of liver damage.**
- Solpadeine Max Soluble Tablets should not be taken by children **below the age of 12 years**, due to the risk of severe breathing problems.

Do not take for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.
Solpadeine Max Soluble Tablets should be used for 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.
Solpadeine Plus Tablets should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

This medicine contains codeine and can cause addiction if you take it continuously for more than three 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 more Solpadeine Plus Tablets than you should
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. Symptoms of paracetamol overdose generally appear in the first 24 hours and may include: unusual paleness, feeling sick, vomiting, loss of appetite and abdominal pain, or patients may be asymptomatic.
If your symptoms continue or your headache becomes persistent, **see your doctor**.

If you forget to take Solpadeine Plus Tablets
Do not take a double dose to make up for a forgotten dose.

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**, **tear flow, runny nose, yawning, muscle pain, widened/dilated pupils**, **difficulty sleeping**, **irritability**, **agitation**, **anxiety**, feeling your heartbeat (**palpitations**), **increased or restless body movements, weakness, abdominal cramps, increased respiration rate or heart rate, increased blood pressure, feeling or 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

Stop taking this medicine and **tell your doctor immediately** if you experience:

- sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness
- swelling of skin or mucous membrane, face, tongue and throat causing breathing difficulties
- Very rare cases of serious skin reactions have been reported, such as:
    - Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN))
    - Inflammation of the skin induced by medicines
    - A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (Acute generalized exanthematous pustulosis)
- Nervousness, dizziness, irritability, drowsiness or restlessness
- **Breathing problems. These are more likely if you have experienced them before when taking other pain-relieving medicines such as ibuprofen and aspirin**
- Unexplained **bruising** or **bleeding**
- **Frequent infections, fever** or **chills**

Other side effects:

Uncommon side effects (affecting 1 in 1,000 to 1 in 100 people):

- Drug withdrawal syndrome

Rare side effects (affecting 1 in 10,000 people to 1 in 1,000 people):

- Allergic reactions

Very rare side effects (affecting less than 1 in 10,000 people):

- Allergic reactions of the skin with rash, itching, sweating, rash of raised red or purple spots, the spots look like small bruises or blood spots, hives
- Cloudy urine

Side effects with frequency not known (frequency cannot be estimated from the available data):

- Liver impairment
- Drug dependency after prolonged use
- Constipation
- Nausea
- Vomiting
- Heartburn
- Dry mouth
- Dizziness
- Nervousness
- Pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine
- Worsening of headache with prolonged use
- Drowsiness
- Difficulty with urination
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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** or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 sight and reach of children.
Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.
Do not use this medicine after the 'EXP' date shown on the pack. Store below 25°C.
Store in the original package in order to protect from light and moisture.

6. Contents of the pack and other 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 Dungarvan Ltd., Co. Waterford, Ireland or Swiss Caps GmbH Grassingerstraße 9, 83043 Bad Aibling, Germany (Aenova Group).

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