Package Leaflet: Information for the user

Solpadeine Soluble Tablets

Paracetamol 500mg, Codeine Phosphate Hemihydrate 8mg and Caffeine 30mg

Please read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told 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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

Solpadeine soluble tablets contains the active substances paracetamol 500 mg and codeine phosphate hemihydrate 8 mg , which are both pain-relieving drugs, and caffeine 30 mg, a stimulant which acts to enhance the pain-relieving effects of paracetamol.

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 pain killers such as paracetamol. Paracetamol also helps to reduce temperature when you have a fever. Codeine has some cough suppressant action.

Solpadeine 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 painkillers such as paracetamol or ibuprofen alone.

Solpadeine soluble tablets provide effective relief from pain, including:

- Headache, including migraine
- Toothache
- Period pain
- Rheumatic pain
- Backache
- Neuralgia
- Relief of cold and flu symptoms

This product should be used only when clearly necessary.

2. What you need to know before you take this medicine

- 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.
- 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 this medicine

- if you are allergic to paracetamol, codeine, caffeine or any of the other ingredients of this medicine (listed in section 6)
- if you are taking other medicines containing paracetamol or codeine
- if you suffer from acute asthma (if you have suffered from recent asthma attacks) or respiratory depression
- in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- if you are breastfeeding
- if you know that you metabolise very rapidly codeine into morphine
- if you are under 12 years old
- if you suffer from 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
- if you suffer from an enlarged prostate (difficulty passing water)
- if you suffer from heart or blood pressure problems
- if you have been told by your doctor that you have an intolerance to some sugars
- 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 sentitive to aspirin
- if you have recently had gall bladder surgery or a similar operation
- if you have chronic alcoholism
- if you have Gilbert's Syndrome (familial non-haemolytic jaundice)
- if you are taking other medicines that can affect the liver
- if you have glucose-6-phosphate dehydrogenase deficiency
- if you have haemolytic anaemia
- if you have glutathione deficiency
- if you are dehydrated
- if you have had poor diet such that the diet causes health problems
- if you weigh less than 50kg
- if you are elderly.

They may reduce the dose or increase the time interval between doses of your medicine.

During treatment with Solpadeine 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).
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 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 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.

Special warnings about addiction and withdrawal
Solpadeine Soluble Tablets contain codeine, which is an opioid medicine.
Repeated use of Solpadeine Soluble Tablets may result in you becoming accustomed to it (needing to take higher doses). Repeated use of Solpadeine Soluble Tablets may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.
If you are taking Solpadeine Soluble Tablets for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harm to the liver. These can be fatal.
If you experience any of the following signs whilst taking Solpadeine Soluble Tablets, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine - When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')

Children and adolescents
Use in children and adolescents **after surgery**:
This medicine 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 or adolescents with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and Solpadeine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- medicines that you have bought yourself such as cough/cold remedies and other painkillers. Many of these will contain paracetamol and/or codeine and must not be taken while you are taking Solpadeine soluble tablets
- if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers (including monoamine oxidase inhibitors-MAOIs)
- medicines used to relax you or to help you sleep (such as benzodiazepines)
- medicines for high cholesterol levels or for the treatment of diarrhoea (cholestyramine)
- medicines to stop you feeling sick or vomiting (domperidone or metoclopramide)
- medicines to prevent blood clots (such as warfarin)
- medicines for the treatment of gout (probenecid)
- medicines for eye infections (chloramphenicol)
- anticonvulsants and medicines used to treat epilepsy (such as barbiturates)
- oral contraceptive steroids
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)
- **pregabalin** and **gabapentin** as there is an increased risk of **respiratory depression.**

Concomitant use of this medicine and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), 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 this medicine together with sedative medicines 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.

Solpadeine with food, drink and alcohol
Do not drink alcohol when taking this medicine.
Avoid excessive intake of caffeine containing products such as coffee, tea and some canned drinks.

Pregnancy, breast-feeding and fertility
Do not use this medicine while you are breastfeeding, it may be present in breast milk.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
This medicine may make you feel drowsy. You should not drive or operate machinery until you know how this medicine affects you.

This medicine contains sodium
This medicine contains 427 mg sodium in each tablet. The maximum recommended daily dose of this medicinal product contains 3416 mg sodium (found in table salt). This is equivalent to 171% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you are taking Solpadeine soluble tablets and have been advised to have a low salt diet.

This medicine contains 50mg sorbitol (E 420) 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.

3. How to take this medicine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults
1-2 tablets every 6 hours as required. Do not take more than 4 doses in 24 hours, equivalent to 8 tablets.
The dose should not be repeated more frequently than every 6 hours.
Elderly patients may require a reduced dose or frequency of dosing.

Use in children and adolescents

Adolescents 16 to 18 years of age
1-2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours.

Adolescents 12 to 15 years of age
1 tablet every 6 hours. Do not take more than 4 tablets in 24 hours.

Children aged less than 12 years:
Solpadeine Soluble Tablets should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

Method of administration
Dissolve the tablets in at least half a glass of water.

Do not take **more than the recommended dose.**

This medicine should not be taken for more than 3 days because of the risk of addiction. If the pain does not improve after 3 days, talk to your doctor for advice. Prolonged use except under medical supervision may be harmful.

If you take more Solpadeine 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.
The symptoms can include: nausea, vomiting, anorexia, pale skin, and abdominal pain, or patients may be asymptomatic. If your symptoms continue or your headache becomes persistent, **see your doctor.**

Patients should be aware of the signs and symptoms of overdose and to seek immediate medical help if they occur. It may be helpful for patients to inform friends or family members so they are also aware of the signs and symptoms described above.

If you forget to take this medicine
Do not take a double dose to make up for a forgotten dose. You must allow at least 6 hours between doses.

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:

- 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 **peeling** or **mouth ulcers.**
- **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**.
- **Liver problems**. Solpadeine Soluble Tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your liver which could be fatal.
- **Severe skin reactions** such as severe blisters and bleeding in the lips, eyes, mouth, nose and genitals and formation of blisters containing pus
- Urinary retention.

In addition, some of the following side effects may occur:
- cloudy urine
- indigestion and stomach cramps
- nervousness, restlessness, irritability and tremor
- hallucinations and nightmares

- fast or irregular heartbeat
- blurred or double vision
- sweating and facial flushing
- dry mouth
- constipation
- feeling dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down.

These effects go away once you stop taking the medicine. If any of these effects occur, or get serious, or if you notice any other side effect not listed in this leaflet, stop taking this medicine, and tell your doctor or pharmacist immediately.

Prolonged regular use, may lead to addiction and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you need to take the medicine for longer periods of time or you need to take more than the recommended dose or feel irritable and restless when you stop taking the medicine, you may be addicted.

If you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting, or if you have previously experienced breathing problems with aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product, stop taking this medicine and tell your doctor immediately.

Taking any type of pain reliever for headaches too often or for a too long period of time can make them worse. If this situation happens to you talk to your doctor or pharmacist.

Frequency "Not known" (frequency cannot be estimated from the available data): 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 HPRA Pharmacovigilance; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store this medicine above 25°C.
Store in original packaging to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What this medicine contains

- The active substances are paracetamol 500mg, codeine phosphate hemihydrate 8mg and caffeine 30mg.
- The other ingredients are sodium hydrogen carbonate, sorbitol (E420), saccharin sodium, sodium laurilsulfate, anhydrous citric acid, anhydrous sodium carbonate, povidone and dimeticone.

What this medicine looks like and contents of the pack

Solpadeine soluble tablets are flat, white soluble tablets, with bevelled edges, plain on one side, break line on the other. They are available in packs of 4, 8, 12, 24, 32, 36, 48 or 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland
All enquiries should be sent to this address.

Manufacturer
GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford
or
Swiss Caps GmbH, Grassingerstraβe 9, 83043 Bad Aibling, Germany (Aenova Group).

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