

Package leaflet: Information for the patient user

Solpadol® Caplets 500mg/30mg Tablets

Paracetamol

Codeine Phosphate Hemihydrate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

What is in this leaflet:

1. What Solpadol is and what it is used for
2. What you need to know before you take Solpadol
3. How to take Solpadol
4. Possible side effects
5. How to store Solpadol
6. Contents of the pack and other information

1. WHAT SOLPADOL IS AND WHAT IT IS USED FOR

The name of this medicine is Solpadol Caplets 500mg/30mg Tablets.

Solpadol belongs to a group of medicines called analgesics (painkillers) and is used to treat severe pain in adults. Solpadol 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.

This product contains codeine. 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLPADOL

Do not take Solpadol:

- 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 are breastfeeding
- If you are allergic to codeine, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- If you have asthma or severe breathing problems
- If you have recently had a head injury
- If you have recently had gall bladder surgery or a similar operation
- If you have raised pressure in the brain
- If you are taking monoamine oxidase inhibitors (used to treat depression) or have taken them in the last 14 days

- If you are an alcoholic or have recently consumed a large amount of alcohol
- If the person going to take the medicine is under 12 years of age.

Warnings and precautions

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 Solpadol 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 Solpadol 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 Solpadol, 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 Solpadol).

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.

Do not take with any other paracetamol containing product.

During treatment with Solpadol, 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).
- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

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.

Sleep-related breathing disorders

Solpadol 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.

Talk to your doctor or pharmacist before taking Solpadol:

- If you have prostate problems (e.g. difficulty in passing water)
- If you have bowel problems
- If you have kidney or liver problems, including alcoholic liver disease
- If you have low blood pressure (hypotension)
- If you have multiple sclerosis
- If you have a history of drug or alcohol abuse
- If you have a condition known as glucose-6-phosphate dehydrogenase (G6PD) deficiency because of the risk of a particular form of anaemia (low number of red blood cells)
- If you have glutathione deficiency
- If you have Gilbert's syndrome (familial non-haemolytic jaundice)
- If you have chronic malnutrition or dehydration
- If you weigh less than 50 kg
- If you are elderly

Other medicines and Solpadol

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Solpadol can affect the way some medicines work. Also, some medicines can affect the way Solpadol works.

Please check with your doctor if you are taking any of the following:

- Metoclopramide (used to treat nausea and vomiting)
- Domperidone

- Buprenorphine
- Nalbuphine
- Pentazocine
- Naltrexone
- Quinidine, used to treat irregular heartbeat
- Fluoxetine, paroxetine, bupropion, used to treat depression
- Cinacalcet, used to treat hyperparathyroidism
- Colestyramine (used to treat high blood cholesterol (fat) levels)
- Chloramphenicol, flucloxacillin, rifampin, antibiotics used to treat infection
- Benzodiazepines, used to treat anxiety, due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.
- Morphine products, used to treat severe pain
- Methadone, used to treat opioid addiction and also severe pain
- Certain cough medicines
- Oral contraceptives ("the pill")
- Drugs which make you sleepy, including alcohol and barbiturates
- Drugs used to thin the blood (e.g. warfarin).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment (see section 2).
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Solpadol with food and drink

You should not drink alcohol while you are taking Solpadol. This is due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.

Children and adolescents

Use in children and adolescents after surgery

Solpadol 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 and adolescents with breathing problems

Solpadol is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Children 12 to 18 years of age who have breathing problems should not take this product. This includes breathing problems while sleeping, or other lung problems

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Solpadol during the last three months of pregnancy or during labour.

Do not take Solpadol while you are breastfeeding. Codeine and morphine pass into breast milk.

Driving and using machines

You may feel dizzy or sleepy while taking Solpadol. You may also have problems with your vision. If this happens, do not drive or use any tools or machines.

Solpadol contains sodium

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. HOW TO TAKE SOLPADOL

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Solpadol, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Solpadol).

Adults (18 years and over):

Take two tablets every 4-6 hours. Do not take more than 8 tablets in 24 hours. Elderly patients may be prescribed a lower dose.

Children aged 16 to 18 years:

One to two tablets every 6 hours to a maximum of four doses in any 24 hours. Do not exceed 8 tablets in 24 hours.

Children (12-15 years):

Take one tablet every 6 hours. Do not take more than 4 tablets in 24 hours.

Solpadol should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

In patients with impaired liver function or Gilbert's syndrome, the dose must be reduced or the dosing interval prolonged.

The maximum daily dose of paracetamol should not exceed 2g/day unless your doctor gives you different advice if:

- You weigh less than 50 kg
- You suffer from mild to moderate liver or kidney disease
- You have Gilbert's syndrome (familial non-haemolytic jaundice)
- You suffer from chronic alcoholism, malnutrition or dehydration

Swallow the Caplets with a drink of water.

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.

Solpadol 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.

If you have kidney failure, leave at least 8 hours between doses.

Whilst taking Solpadol you should not take any other medicines which contain paracetamol.

Do not exceed the recommended dose. Do not take for longer than your doctor tells you to.

If you take more Solpadol than you should

Immediate medical advice should be sought in the event of overdosage, even if you feel well, because of the risk of irreversible liver damage.

If you forget to take Solpadol

If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take two doses at or near the same time. Remember to leave at least 6 hours between doses.

If you stop taking Solpadol

Long term usage of Solpadol may lead to tolerance and dependence. If you have taken regular daily doses of Solpadol for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side-effects you should know about Solpadol

- Taking a painkiller for headaches too often or for too long can make them worse.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the caplets.

Stop taking Solpadol and see a doctor or go to a hospital straight away if:

- You experience skin rash, swelling or itching, difficulty in breathing, feeling dizzy. These symptoms could be signs of an allergic reaction.
 - You experience blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.
 - You have a severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolysis'.
- Very rare cases of serious skin reactions have been reported.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- You become constipated
- You feel sick (nauseous) or start being sick (vomiting)
- You have dizziness, light headedness, drowsiness, confusion
- You have difficulty in passing water (urine)
- You have a seizure
- You have dry mouth
- You have an itchy skin rash (pruritus)
- You have a ringing in your ears (tinnitus)

- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)
- You have difficulty breathing, wheezing, tightness in the chest (bronchospasm)
- You have extreme feelings of joy and happiness (euphoria)
- You have extreme feelings of sadness and depression (dysphoria)
- You have blurred vision due to the pupil of the eye becoming smaller (myosis)
- You start breathing more quickly than normal and the skin around your mouth is a blue colour. This could be symptoms of respiratory depression.
- You feel more tired than usual, your skin and/or whites of your eyes are a yellowish colour. These could be symptoms of haemolytic anaemia
- You have no appetite, have abdominal pain and feel generally unwell and your skin and/or whites of your eyes are a yellowish colour. These could be symptoms of cytolytic hepatitis, a serious liver disease.
- Excess acid in the blood caused by too much pyroglutamic acid due to low glutathione levels.

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).

Problem affecting a valve in the intestines (sphincter of Oddi dysfunction)

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 SOLPADOL

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.

Solpadol Caplets 500mg/30mg Tablets should not be stored above 25°C. Store in the original package in order to protect the product from moisture.

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

Keep this medicine out of the sight and reach of children.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Solpadol contains

The active substances are 500mg Paracetamol and 30mg Codeine Phosphate Hemihydrate.

The other ingredients are pregelatinised starch, maize starch, microcrystalline cellulose, talc, croscarmellose sodium, povidone, stearic acid, magnesium stearate, potassium sorbate.

What Solpadol looks like and contents of the pack

Solpadol Caplets 500mg/30mg Tablets are white to off white capsule-shaped tablets with flat sides marked 'SOLPADOL' on one side and blank on the reverse.

Solpadol Caplets 500mg/30mg Tablets are supplied in cartons of 4, 10, 60 and 100. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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**only the site which performs batch release will be included in the leaflet*

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