

PATIENT INFORMATION LEAFLET

SOLPADOL 30mg/500mg CAPLETS

Codeine Phosphate and Paracetamol

This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Is this leaflet hard to see or read?
Phone +353-1-5742410 for help

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please 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 any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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 your medicine is Solpadol 30mg/500mg Caplets (called Solpadol throughout this leaflet). This medicine has been prescribed for you for the relief of severe pain. Solpadol can be used in children 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. Solpadol contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. It also contains paracetamol, another analgesic to relieve pain. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Solpadol

Important things you should know about Solpadol

Do not take for longer than your doctor tells you to.

Taking this medicine regularly, particularly for a long time can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction.

Overuse and misuse can lead to overdose and/or death.

Taking a painkiller for headaches too often or for too long can make them worse.

Do not take Solpadol and tell your doctor if:

x You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients in your medicine (listed in Section 6). Signs of an allergic reaction include a rash and breathing problems.

There can also be swelling of the legs, arms, face, throat or tongue.

x You have severe asthma attacks or severe breathing problems.

x You have recently had a head injury.

x You have been told by your doctor that you have increased pressure in your head.

Signs of this include: headaches, being sick (vomiting) and blurred eyesight.

x You have recently had an operation on your liver, gallbladder or bile duct (biliary tract).

x You are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypromine (see 'Other medicines and Solpadol').

x You are an alcoholic.

x The person going to take the caplets is under 12 years of age.

x You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.

x If you know that you metabolise very rapidly codeine into morphine.

x If you are breastfeeding.

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

Warnings and precautions

Check with your doctor before taking Solpadol if:

- You are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- You feel you need to take more of Solpadol 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. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- You have severe kidney or liver problems.
- You have problems passing water or prostate problems.
- You have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel.
- You are elderly.
- You are sensitive to aspirin or other medicines used for the treatment of inflammation. (Non Steroidal Anti-inflammatory Drugs) such as Ibuprofen.

- You are taking a benzodiazepine.
- You know you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable to you.
- You are taking a medicine that induces CYP3A4 enzyme activity such as rifampicin.

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

Other medicines and Solpadol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Solpadol can affect the way some other medicines work. Also, some other medicines can affect the way Solpadol works.

Concomitant use with sedative medicines

Concomitant use of Solpadol 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 Solpadol 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.

Solpadol contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine, and tell your doctor, if you are taking:

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine.

Tell your doctor or pharmacist if you are taking any of the following medicines, or have taken them in the past two weeks:

- Medicines used to thin the blood such as warfarin.
- Chloramphenicol - an antibiotic used for infections.
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- Colestyramine - for lowering blood cholesterol levels.
- The oral contraceptive pill.
- Medicines such as quinidine, fluoxetine, paroxetine, bupropion, cinacalcet, methadone or rifampicin, as these may alter the effect of Solpadol.

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

Solpadol and food and drink

You should not drink alcohol while you are taking these caplets. This is because Solpadol can change the way alcohol affects you.

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 breastfeeding

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

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

Do not take Solpadol while you are breastfeeding as codeine and morphine passes into breast milk and will affect your baby.

Driving and using machines

Solpadol 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.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per 30 mg/500 mg caplet, that is to say essentially 'sodium-free'.

Changing or stopping treatment

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.

3. How to take Solpadol

Your prescriber should have discussed with you, how long the course of caplets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Always take Solpadol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Do not take more than the recommended dose.
- Do not take for longer than your doctor tells you to.
- Take this medicine by mouth.
- Swallow the caplets whole with a drink of water.

Adults: 2 caplets every 4 to 6 hours when necessary up to a maximum of 8 caplets in 24 hours.

Elderly people may be prescribed a lower dose.

Children aged 16 to 18 years: 1-2 caplets every 6 hours when necessary up to a maximum of 8 caplets in 24 hours.

Children aged 12 to 15 years: 1 caplet every 6 hours when necessary up to a maximum of 4 caplets in 24 hours.

This medicine should not be taken for more than 3 days. If pain does not improve after 3 days, talk to your doctor for advice

Children under 12 years: Solpadol should not be given to children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Solpadol than you should

- Tell your doctor or go to your nearest hospital casualty department straight away- even if you feel well. This is because of the risk of delayed, serious liver damage.
- Remember to take any remaining caplets and the pack with you. This is so the doctor knows what you have taken.

If you have forgotten 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 4 hours between doses.

If you stop taking Solpadol

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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.
- Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?")

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

- You have difficulty in breathing or you feel dizzy.
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction**.
- You get serious skin reactions. Very rare cases have been reported.
- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is very rare side effect.

Other side effects have been reported:*Codeine-related side effects:*

Frequency and severity are determined by dosage, duration of treatment and individual sensitivity:

- Constipation.
- Feeling sick (nausea), being sick (vomiting).
- Dizziness, light-headedness, drowsiness, confusion.
- Difficulty in passing water (urine).
- Becoming dependent on codeine.

Paracetamol-related side effects:

Very Rare (may affect up to 1 in 10,000 people):

- You get infections or bruise more easily than usual. This could be because of a blood problem (such as neutropenia or thrombocytopenia)

Frequency not known:

- Difficulty breathing, wheezing, tightness in the chest (bronchospasm).
- Low blood pressure (hypotension) with high doses.
- You get infections more easily than usual. This could be because of a blood problem called agranulocytosis.

Drug withdrawal

When you stop taking Solpadol, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Solpadol, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber.
- You feel you need to use more than the recommended dose.
- You are using the medicine for reasons other than prescribed.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

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.

5. How to store Solpadol

Keep this medicine in a safe place out of the sight and reach of children. Do not use this medicine after the expiry date shown on the pack. Store your medicine in the original packaging in order to protect from moisture. Do not store above 25°C. 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 30mg/500mg Caplets contain

- The active substances of Solpadol 30mg/500mg Caplets are codeine phosphate and paracetamol. Each caplet contains 30mg of codeine phosphate and 500mg of paracetamol.

- The other ingredients are pregelatinised starch, maize starch, potassium sorbate, microcrystalline cellulose, stearic acid, talc, magnesium stearate, povidone and croscarmellose sodium (type A).

What Solpadol 30mg/500mg Caplets look like and contents of pack

Solpadol 30mg/500mg caplets are white, capsule shaped tablets (caplets), marked with the word 'SOLPADOL' on one face. They come in cartons of 4, 10, 24, 30, 60 and 100 caplets. Not all pack sizes may be marketed.

The Marketing Authorisation Holder is Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland. Tel: +353-1-5742410 email: medicalinformation@phoenixlabs.ie

The Manufacturer is

LABORATORI FUNDACIÓ DAU, C/C, 12-14, Pol. Ind. Consorci Zona Franca, 08040 Barcelona, Spain

This leaflet was last updated in September 2023