

# PATIENT INFORMATION LEAFLET

SOLPADOL 30mg/500mg CAPLETS

Codeine Phosphate and Paracetamol

**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 effects not listed in this leaflet, please tell your doctor or pharmacist

## **In this leaflet:**

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## **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). Solpadol contains two different medicines called codeine phosphate and paracetamol.

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

## **2. Before you take Solpadol**

### **Important things you should know about Solpadol**

- Do not take for longer than your doctor tells you to
- 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
- Taking a painkiller for headaches too often or for too long can make them worse

### **Do not take Solpadol and tell your doctor if:**

- You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients in your medicine (listed in Section 6: Further information). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- You have severe asthma attacks or severe breathing problems

- You have recently had a head injury
- 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
- You have recently had an operation on your liver, gallbladder or bile duct (biliary tract)
- 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 tranylcypamine (see ‘Taking other medicines’)
- You are an alcoholic
- The person going to take the caplets is under 12 years of age.

Do not take Solpadol if any of the above apply to you.

**Take special care and check with your doctor before taking Solpadol if:**

- 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

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

**Taking other medicines**

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 other medicines work. Also, some other medicines can affect the way Solpadol works.

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

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, tranylcypamine

Tell your doctor if you are taking any of the following medicines:

- Medicines which make you drowsy or sleepy (CNS depressants)
- 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

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

### **Taking Solpadol with 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.

### **Pregnancy and breast-feeding**

Talk to your doctor before taking these caplets if:

- You are pregnant, think you may be pregnant or plan to get pregnant
- You are breast-feeding or planning to breast-feed

Usually it is safe to take Solpadol while breast feeding as the levels of the active ingredients of this medicine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels in their breast milk. If any of the following side effects develop in you or your baby, stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

### **Driving and using machines**

You may feel dizzy or sleepy while taking Solpadol. If this happens, do not drive or use any tools or machines.

### **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**

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

### **Adults and children over 12**

- Take this medicine by mouth
- Swallow the caplets whole with a drink of water
- The usual dose of Solpadol is 2 caplets, taken together
- Wait at least 4 hours before taking another dose
- Do not take more than 8 caplets in any 24-hour period
- Elderly people may be prescribed a lower dose

## **Children**

Solpadol should not be given to children under 12 years of age.

### **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.

## **4. Possible side effects**

As with all medicines, Solpadol can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

### **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 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 to Solpadol

### **Talk to your doctor straight away if you notice the following serious side effect:**

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect

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

- Constipation
- Feeling sick (nausea), being sick (vomiting)

- Dizziness, light-headedness, drowsiness, confusion
- Difficulty in passing water (urine)
- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)

If any of the side effects gets serious, lasts longer than a few days or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. How to store Solpadol**

Keep this medicine in a safe place out of the reach and sight 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.

Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

## **6. Further 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 sold.

### **The Marketing Authorisation Holder is**

Sanofi- Aventis  
 One Onslow Street  
 Guildford  
 Surrey  
 GU1 4YS  
 UK

Tel:01483 505515  
Fax: 01483 535432  
email: uk-medicalinformation@sano fi-aventis.com

**The Manufacturer is**

Fawdon Manufacturing Centre  
Edgefield Avenue  
Fawdon  
Newcastle upon Tyne  
NE3 3TT  
UK

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