

## **Package leaflet: Information for the user**

### **Solpadeine capsules**

Paracetamol 500mg, codeine phosphate hemihydrate 8mg and caffeine 30mg

**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 capsules 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 capsules 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. This medicine is not recommended for use in children aged 12 years to 18 years with compromised respiratory function for the symptomatic treatment of cough and/or cold.

Solpadeine capsules 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**

##### **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 suffer from acute asthma (if you have suffered from recent asthma attacks);
- 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 suffer from an enlarged prostate (difficulty passing water);
- if you suffer from any bowel disorders;
- if you suffer from any liver or kidney problems;
- 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 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 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 Capsules, 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).

Talk to your doctor or pharmacist before taking Solpadeine Capsules:

- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances

Taking codeine (an active ingredient of this medicine) regularly for a long time can lead to addiction and misuse, which may result in overdose and/or death.

Do not take this medicine longer than needed. Do not give this medicine to anyone else.

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.

### **Special warnings about addiction**

This product contains codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to addiction and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time or think you are suffering from withdrawal symptoms, it is important to consult your doctor or pharmacist.

### **Children and adolescents**

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. 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 Capsules;
- 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).

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 during pregnancy and 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.

### **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 capsules every 4-6 hours. Do not take more than 4 doses in 24 hours, equivalent to 8 capsules.

The dose should not be repeated more frequently than every 4 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 capsules every 6 hours. Do not take more than 8 capsules in 24 hours.

#### Adolescents 12 to 15 years of age

1 capsule every 6 hours. Do not take more than 4 capsules in 24 hours.

#### Children aged less than 12 years:

Codeine should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

#### *Method of administration*

Swallow Solpadeine capsules with water.

Do not exceed the stated dose.

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.

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 you forget to take this medicine**

Do not take a double dose to make up for a forgotten dose. You must allow at least 4 hours between doses.

### **4. Possible side effects**

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

Prolonged regular use, except under medical supervision, 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. In any of these apply to you, it is important that you talk to your doctor.

This medicine may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down. You may also become constipated. You may experience problems with your blood which means that you may bleed or bruise easily (known as thrombocytopenia) or which makes it more likely that you may get an infection (known as agranulocytosis).

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).

Some of the following side effects may occur:

- allergic reactions such as skin rash or itching, sweating, sometimes with breathing problems, or swelling of the lips, tongue, throat or face;
- unusual bleeding or bruising under the skin;
- skin rash or peeling of the skin which may be accompanied by mouth ulcers;
- severe skin reactions such as severe blisters and bleeding in the lips, eyes, mouth, nose and genitals and formation of blisters containing pus;
- blood disorders including low platelet count (making you slow to heal and bruise easily) and low white blood cell count (making you more likely to get infections);
- cloudy urine or urinary retention;
- nervousness and tremor;
- hallucinations and nightmares;
- fast or irregular heartbeat;
- blurred vision;
- facial flushing;
- constipation.

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.

### **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](http://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 maize starch, magnesium stearate, titanium dioxide (E171), erythrosine (E127), patent blue (E131), quinoline yellow (E104), gelatin.

### **What this medicine looks like and contents of the pack**

Solpadeine capsules are gelatin capsules with a red, opaque cap and a white, opaque body plain on both the sides. They are available in packs of 6, 12, 24, 32, 36, 48, 60, 72 or 96 capsules. 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**

Omega Pharma International NV, Venecoweg 26, Nazareth, 9810, Belgium  
or  
Swiss Caps GmbH  
Grassingerstraße 9  
83043 Bad Aibling  
Germany (Aenova Group).

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