

PACKAGE LEAFLET: INFORMATION FOR THE USER

Solpadol® 500mg/30mg Effervescent Tablets (paracetamol / codeine phosphate hemihydrate)

This product is available as 'Co-codamol 30/500 Effervescent Tablets' in other jurisdictions.

Solpadol is available as Solpadol Caplets 500mg/30mg Tablets and Solpadol 500mg/30mg Effervescent Tablets.

This leaflet applies to Solpadol 500mg/30mg Effervescent Tablets which will be referred to as Solpadol throughout this leaflet.

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 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 any side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Solpadol is and what it is used for
2. Before you take Solpadol
3. How to take Solpadol
4. Possible side effects
5. How to store Solpadol
6. Further information

1. What Solpadol is and what it is used for

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

2. Before you use Solpadol

Do not take Solpadol if:

- You are pregnant or are breast-feeding
- You are allergic to codeine, paracetamol or any of the other ingredients
- You have asthma or severe breathing problems
- You have recently had a head injury
- You have recently had gall bladder surgery or a similar operation
- You have raised pressure in the brain
- You are taking monoamine oxidase inhibitors (used to treat depression) or have taken them in the last 14 days
- You are an alcoholic or have recently consumed a large amount of alcohol
- You are under 12 years of age.

Take special care with Solpadol

Special care is needed (check with your doctor) if:

- You have prostate problems (e.g. difficulty in passing water)
- You have bowel problems
- You have kidney or liver problems
- 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.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (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, it is important to consult your doctor.

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 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
- colestyramine (used to treat high blood cholesterol (fat) levels)
- chloramphenicol or flucloxacillin, both antibiotics used to treat infection
- benzodiazepines, used to treat anxiety
- 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).

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

Taking Solpadol with food and drink

You should not drink alcohol while you are taking Solpadol. This is because Solpadol changes the way alcohol affects you.

Pregnancy and breast-feeding

Solpadol should not be used in pregnancy and during labour.

Solpadol must not be used during breast-feeding, as some women may have higher levels in their breast milk, resulting in increased risk of side effects for mother and infant.

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.

Important information about some of the ingredients of Solpadol

Each Solpadol tablet contains 388mg sodium. This should be taken into consideration by patients on a controlled sodium diet. These tablets also contain sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Solpadol.

3. How to take Solpadol

The usual dose of Solpadol is 2 effervescent tablets not more often than every 4 hours.

Do not take more than 8 effervescent tablets in any 24 hour period. Elderly patients may be prescribed a lower dose. If you have kidney failure, leave at least 8 hours between doses.

Dissolve the effervescent tablets in at least half a tumbler of water before taking. 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

Tell your doctor straight away 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. Take the pack with you, so that the doctor knows what you have taken.

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 4 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, Solpadol can cause side effects, although not everybody gets them.

If any of the following become troublesome or lasts for longer than a few days you should tell your doctor:

- you become constipated
- you feel nauseous (sick), or start vomiting (being sick)
- you feel dizziness, light headedness
- you feel drowsy
- you feel confused
- you develop a cough with wheezing in your chest. This could be a symptom of bronchospasm.
- You have difficulty passing urine
- you get infections or bruise more easily

There have been a few reports of blood problems associated with paracetamol containing products but these were not necessarily due to paracetamol. Taking a painkiller for headaches too often or for too long can make them worse.

Tell your doctor straight away if you notice any of the following side effects:

- skin rash, swelling or itching, difficulty in breathing. These symptoms could be signs of an allergic reaction.
- stomach pain, which may reach to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.
- If you have an allergic reaction accompanied by chest pain this could be a symptom of a serious disorder called Kounis syndrome.
- 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 (miosis)
- 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 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'.
- 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.

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 (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST Pharmacovigilance
Section
Irish Medicines Board,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2, Ireland.
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
email: imbpharmacovigilance@imb.ie

5. How to store Solpadol

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not store above 25°C.

Store in the original package in order to protect from moisture. Do not use Solpadol 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.

If your tablets appear to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Solpadol contains

Each tablet contains 500mg paracetamol and 30mg codeine phosphate hemihydrate.

Also contains: sodium bicarbonate, citric acid anhydrous, sodium carbonate anhydrous, sorbitol powder (E420), saccharin sodium, povidone, dimethicone and sodium lauryl sulphate.

What Solpadol looks like and contents of the pack

Solpadol are white, bevelled-edge tablets, scored on one face and plain on the reverse.

Solpadol are available in packs of 10 strips (100 tablets).

Manufacturer

Solpadol is manufactured by: Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT, UK.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/191/2

POM

Leaflet revision and issue dated (ref): 10.02.14

Solpadol® is a registered trademark of Omega Pharma Innovation & Development NV.