

Package leaflet: Information for the user

Solpa-Plus with Caffeine Soluble Tablets

paracetamol 500 mg, codeine phosphate hemihydrate 12.8 mg, caffeine 30 mg

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked.
- You should only take this product for a maximum of 3 days at a time. If you need to take it for longer than 3 days you should see your doctor or pharmacist for advice.
- This medicine contains codeine, which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take this medicine for headaches for more than 3 days, it can make them worse.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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.

What is in this leaflet

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1. What Solpa-Plus Tablets is and what it is used for

Solpa-Plus Tablets can be used in patients over 12 years of age for the short-term relief of moderate pain which requires stronger relief than other painkillers such as paracetamol, ibuprofen or aspirin alone.

It can be used for headaches, migraine with or without warning signs (aura), dental pain (including pain after extraction), period pain, neuralgia, strains and sprains, backache, pain in bones and joints arising from arthritis and rheumatism, sciatica.

The tablets contain three active ingredients: paracetamol, codeine and caffeine. Codeine and paracetamol are both painkillers. 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 painkillers. Caffeine acts to further help the effectiveness of paracetamol. The triple action of the ingredients provides fast acting relief of moderate pain.

2. What you need to know before you take Solpa-Plus Tablets

- This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take a painkiller for headaches for more than 3 days, it can make them worse.

Do not take Solpa-Plus Tablets:

- if you have ever had an allergic reaction to paracetamol, codeine, caffeine or to any of the other ingredients (listed in Section 6)
- if you are taking other medicines containing paracetamol and codeine

- if you are under 12 years
- if you are breastfeeding
- if you have breathing difficulties
- if you suffer from chronic constipation
- 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

Talk to your doctor or pharmacist before you take this medicine:

- if you have liver or kidney disease, including alcoholic liver disease, or Gilbert's Syndrome (familial non-haemolytic jaundice) The dose must be reduced or the dosing interval prolonged
- If you are taking medicines that affect your liver.
- if you have bowel problems including blockage of the bowel
- if you have had an operation to remove your gall bladder
- if you have asthma and are sensitive to aspirin
- if you have hypotension, hypothyroidism, head injury or raised intracranial pressure
- if you are on a controlled sodium diet. Each tablet contains 427 mg of sodium
- if you have been told by your doctor that you have **intolerance to some sugars**, glucose-6-phosphatedehydrogenase deficiency or glutathione deficiency
- if you have chronic alcoholism, malnutrition or dehydration
- if you are elderly, adult or adolescent weighting less than 50 kg
- Elderly patients may require a reduced dose. Ask your doctor or pharmacist for advice

Warnings and precautions

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.

Check with your doctor before use if you have liver or kidney problems, are underweight (<50kg), become malnourished or regularly drink alcohol as this may increase your risk of liver damage. You may need to reduce the amount of paracetamol that you take or avoid using this product altogether.

Talk to your doctor or pharmacist before taking Solpa-Plus Tablets:

- 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.

Children and adolescents

Do not give this medicine to children under 12 years old.

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.

Other medicines and Solpa-Plus Tablets

Tell your doctor or pharmacist if you are taking any other medicines; particularly: metoclopramide or

domperidone (for nausea [feeling sick] or vomiting [being sick]); colestyramine (to lower blood cholesterol); monoamine oxidase inhibitors (MAOIs) prescribed for depression in the last 2 weeks or substances that make you drowsy (e.g. sedatives, antidepressants or alcohol).

If you take a blood thinning drug (anticoagulants e.g. warfarin and coumarins) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding, but you can still take occasional doses of Solpa-Plus Tablets at the same time as anticoagulants.

If you are taking probenecid speak to your doctor as the dose of Solpa-Plus Tablets may need to be reduced.

If you are taking sedative, tranquilizers and decongestants as Solpa-Plus Tablets contains caffeine which can interfere with or enhance their effects.

Other medicines and paracetamol

Please inform your doctor or pharmacist if you are taking:

- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Concomitant use of 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 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.

Pregnancy and breast-feeding

Talk to your doctor before taking Solpa-Plus Tablets if you are pregnant. Do not take Solpa-Plus Tablets while you are breast-feeding. Codeine and morphine pass into breastmilk.

Driving and using machines

Do not drive or operate machinery if taking Solpa-Plus Tablets as it can cause dizziness or sedation.

Solpa-Plus Tablets contains sodium

The maximum recommended daily dose of this medicinal product (8 tablets) contains 3416 mg sodium (found in table salt). This is equivalent to 171% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Solpa-Plus Tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

Solpa-Plus Tablets contains sorbitol

This medicine contains 50 mg sorbitol in each tablet.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Solpa-Plus Tablets

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

Adults:

Take 1 to 2 tablets dissolved in at least a tumbler of water (200 ml), every 4-6 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets (equivalent to paracetamol 4 g and 102.4 mg Codeine phosphate hemihydrate and caffeine 240 mg) in 24 hours.

Elderly:

Elderly, frail and immobile patients may require a reduced dose.

Renal Impairment:

It is recommended, when giving paracetamol to patients with renal failure, to reduce the dose and to increase the minimum interval between each administration to at least 6 hours.

Adults:

Glomerular filtration rate	Dose
10-50 ml/min	500 mg every 6 hours
<10ml/min	500 mg every 8 hours

Hepatic Impairment:

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

Adolescents 16-18 years of age:

Take 1 to 2 tablets dissolved in at least a tumbler of water (200ml) every 6 hours as required.

- Do not take more frequently than every 6 hours.
- Do not take more than 8 tablets (equivalent to paracetamol 4 g and 102.4 mg Codeine phosphate hemihydrate and caffeine 240 mg) in 24 hours.

Adolescents 12 -15 years of age:

Take 1 tablet dissolved in at least a tumbler of water (200 ml), every 6 hours as needed.

- Do not take more frequently than every 6 hours.
- Do not take more than 4 tablets (equivalent to 2 g paracetamol and 51.2 mg codeine phosphate hemihydrate and caffeine 120 mg) in 24 hours.
- Do not take more than the recommended dose.

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

- If you are: elderly, adults or adolescents weighting less than 50 kg
- If you suffer from mild to moderate liver or kidney problem
- If you have Gilbert's syndrome (familial non-haemolytic jaundice)
- If you suffer from chronic alcoholism, malnutrition or dehydration

Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty sleeping, shaking and uncomfortable feeling in the chest.

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.

Use in children and adolescents under 12 years of age

Solpa-Plus Tablets should not be used by patients under 12 years of age due to risk of severe breathing problems.

Possible withdrawal effects

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. When you stop taking it you may get withdrawal symptoms.

If your symptoms continue or your headache becomes persistent, see your doctor

If you take more Solpa-Plus Tablets than you should

Talk to a doctor if you take too much of this medicine at once, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take Solpa-Plus Tablets

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking the medicine and tell your doctor immediately if you experience:

- Dry mouth, nausea and vomiting if you have recently had your gall bladder removed
- Acute pancreatitis (inflammation of the pancreas) which may result in severe stomach pain.
- Allergic reactions which may be severe appearing as skin rash or mouth ulcers sometimes with flu like symptoms, itching sometimes with swelling of the mouth/face or shortness of breath, skin peeling
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Difficulty in urinating
- Cloudy urine

Other side effects

- Nervousness and dizziness
- Constipation

Very rare cases of serious skin reactions have been reported.

How do I know if I am addicted?

If you take medicine according to the instructions on the pack, it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor.

- You need to take the medicine for longer periods of time
- You need to take more than the recommended dose
- When you stop taking the medicine you feel very unwell but you feel better once you start taking the medicine again.

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 HPRAs 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 Solpa-Plus Tablets

Keep this medicine out of the sight and reach of children. Do not store 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 strip and the carton after "EXP". The expiry date refers to the last day of that month.

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 Solpa-Plus Tablets contains

- The active substances are paracetamol, codeine phosphate hemihydrate and caffeine. Each tablet contains 500 mg paracetamol, 12.8 mg codeine phosphate hemihydrate, 30mg caffeine.
- The other ingredients are: Sorbitol (E420), sodium saccharin, sodium bicarbonate, sodium laurilsulfate, citric acid, sodium carbonate, povidone k-25 and dimeticone 350.

What Solpa-Plus Tablets looks like and contents of the pack

Solpa-Plus Tablets are White bevel-edged scored tablets, 25mm in diameter.

The score line is non-functional and not to divide the tablet into equal doses. Pack sizes: 8, 10, 12, 16, 20, 24 or 32 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland

Manufacturer

GlaxoSmithKline Dungarvan Limited Knockbrack Dungarvan Co. Waterford, Ireland or
Swiss Caps GmbH Grassingerstrasse 9 83043 Bad Aibling Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Romania	Solpadeine Forte 500 mg/12,8 mg/30 mg comprimate efervescente Tablets
Poland	Solpa-Plus with Caffeine Soluble Tablets
Ireland	Solpa-Plus with Caffeine Soluble Tablets Paracetamol 500mg, Codeine phosphate hemihydrate 12.8mg, Caffeine 30mg
Cyprus	Solpa-Plus with Caffeine Soluble Tablets

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