

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

### **Solpa-Plus Tablets**

paracetamol/codeine phosphate hemihydrate

- 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 before you start taking 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 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.

#### **What is in this leaflet**

1. What Solpa-Plus Tablets is and what it is used for
2. What you need to know before you take Solpa-Plus Tablets
3. How to take Solpa-Plus Tablets
4. Possible side effects
5. How to store Solpa-Plus Tablets
6. Contents of the pack and other information

#### **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, backache, muscle ache, neuralgia, pain in bones and joints arising from arthritis and rheumatism, strains and sprains, sciatica.

The tablets contain two active ingredients; paracetamol and codeine. 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. The dual 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, other opioid painkillers or any of the ingredients (listed in Section 6)
- if you are taking other medicines containing paracetamol or codeine
- 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

### **Ask your doctor before you take this medicine:**

- if you have liver or kidney disease, including alcoholic liver disease
- 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 Gilbert's syndrome (familial non-haemolytic jaundice)
- 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 malnutrition or dehydration
- if you are elderly, adult or adolescent weighting less than 50 kg
- if you have hypotension, hypothyroidism, head injury or raised intracranial pressure.

### **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.

Talk to your doctor or pharmacist before taking this medicine:

- 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.

- ~~If you are taking medicines that affect your liver.~~

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.

### **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:**

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed 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 medicines 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.

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 Solpa-Plus Tablets 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 Solpa-Plus Tablets 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**

Solpa-Plus Tablets should be avoided during pregnancy unless you have been advised by your doctor to take this product.

Do not take Solpa-Plus Tablets while you are breast-feeding. Codeine and morphine pass into breast milk.

### **Driving and using machines**

Do not drive or operate machinery if taking Solpa-Plus Tablets causes dizziness or sedation

### **Solpa-Plus Tablets contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Solpa-Plus Tablets**

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.

### Adults:

Take 2 tablets with water every 4-6 hours as needed.

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

### 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:

<b>Glomerular filtration rate</b>	<b>Dose</b>
10-50 ml/min	500mg every 6 hours
<10ml/min	500mg 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 2 tablets with water, every 6 hours as needed.

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

### Adolescents 12-15 years of age:

Take 1 tablet with water, every 6 hours as needed.

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

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

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

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

If you are unsure talk to your doctor for advice.

### **Use in children and adolescents under 12 years of age**

Solpa-Plus Tablets is not recommended for patients under 12 years of age 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 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.

### **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:

- 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 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 <Product name>**

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 from moisture.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP: Expiry date refers to the last date 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 and codeine phosphate hemihydrate. Each

- tablet contains 500 mg paracetamol and 12.8 mg codeine phosphate hemihydrate.
- Other ingredients are: **tablet core** Starch pregelatinised, povidone K25, maize starch, talc, magnesium stearate, stearic acid, microcrystalline cellulose, croscarmellose sodium. **tablet coating** lactose monohydrate, hypromellose, macrogol 4000, quinoline yellow (E 104), erythrosine (E 127) and titanium dioxide (E 171).

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

<Product name> are red film coated, capsule shaped tablets of 15.8 mm x 8.4 mm dimension packed in blister pack.

Pack sizes: 6, 10, 12, 16, 20, 24, 30 or 32 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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

### **Manufacturer**

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:**

Ireland	Solpa-Plus Tablets Paracetamol 500 mg Codeine Phosphate Hemihydrate 12.8 mg
Poland	Paracetamol 500mg + Codeine Phosphate 12.8mg Hemihydrate Omega Pharma

**This leaflet was last revised in March 2023**