

Package leaflet: Information for the user

Solpa-Extra 500mg/65mg Soluble Tablets Paracetamol/Caffeine

Read all of this leaflet carefully 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 after 3 days.

What is in this leaflet

1. What Solpa-Extra Soluble Tablets is and what it is used for
2. What you need to know before you take Solpa-Extra Soluble Tablets
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1. What Solpa-Extra Soluble Tablets is and what it is used for

Solpa-Extra Soluble Tablets contain two active ingredients. Paracetamol is a painkiller and also reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol. The dual action of the ingredients provides fast and effective pain relief from headache and migraine with or without warning signs (aura). They can also relieve backache, muscle and joint pain, toothache, period pain, neuralgia, sore throat and the fever, aches and pains of colds and flu.

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

Do not take Solpa-Extra Soluble Tablets:

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

Warnings and precautions

Talk to your doctor or pharmacist before using Solpa-Extra Soluble Tablets;

- If you have **liver or kidney disease**, including **alcoholic liver disease**
- If you have asthma and are sensitive to acetylsalicylic acid
- 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 haemolytic anaemia, chronic malnutrition or dehydration
- If you are an adult or adolescent weighing less than 50 kg
- If you are over 65 years of age
- If you are on a **controlled sodium diet**.

Children and adolescents Do not give this medicine to children below the age of 12 years.

Other medicines and Solpa-Extra Soluble Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]) or cholestyramine (to lower blood cholesterol). If you take blood thinning drugs (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-Extra Soluble Tablets at the same time as anticoagulants. If you are taking probenecid speak to your doctor as the dose of Solpa-Extra Soluble Tablets may need to be reduced. Tell your doctor if you are taking sedative, tranquilizers and decongestants as Solpa-Extra Soluble Tablets contains caffeine which can interfere with or enhance their effects.

Pregnancy and breast feeding

Due to the caffeine content of this product **it should not be used** if you are **pregnant or breast feeding**, unless advised by a physician.

Driving and using machines

Solpa-Extra Soluble Tablets has no effect on your ability to drive and use machines.

Solpa-Extra Soluble Tablets contains sodium

This medicine contains 427 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 21% of the recommended maximum daily dietary intake of sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

Solpa-Extra Soluble Tablets contains sorbitol

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-Extra Soluble 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 (including elderly) and adolescents aged 16 years and over:

Take 1 to 2 tablets dissolved in at least half a tumbler of water, every 4 to 6 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not exceed 4 doses, equivalent to 8 tablets (4000mg paracetamol/520mg caffeine/24h)

The maximum daily dose of paracetamol should not exceed 2000mg/day (4 tablets/24h) unless your doctor gives you different advice:

- If you suffer from liver or kidney problems
- If you have Gilbert's syndrome
- If you suffer from chronic alcoholism, malnutrition or dehydration
- If you weigh less than 50 kg

In patients with impaired kidney or liver function and patients with Gilbert Syndrome, the dose must be reduced or the dosing interval prolonged. Ask your doctor for advice.

Elderly: reduction of dose may be recommended if you are frail or immobile.

Adolescents 12-15 years of age:

Take 1 tablet dissolved in at least half a tumbler of water, every 4 to 6 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not take more than 4 tablets (2000mg paracetamol/260mg caffeine) in 24 hours.
- **Do not take more than the recommended dose.**
- **Do not give to children under 12 years.**
- **Avoid too much caffeine in drinks like coffee and tea.**

High caffeine intake can cause **difficulty sleeping, shaking** and an **uncomfortable feeling in the chest.**

Use in children and adolescents under 12 years of age

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

If you take more Solpa-Extra Soluble 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-Extra Soluble 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. A small number of people have had side effects.

Stop taking the medicine and tell your doctor immediately if you experience:

- **Allergic reactions** which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- **Skin rash or peeling, or mouth ulcers**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and acetylsalicylic acid
- Unexplained **bruising or bleeding**
- **Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.**
- Cloudy urine

Other side effects:

- Nervousness and dizziness
- In very rare cases decrease in the number of white blood cells (neutropenia and leukopenia) may occur.
- Very rare cases of serious skin reactions have been reported.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 16762517. Website: <http://www.hpra.ie>; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solpa-Extra Soluble 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-Extra Soluble Tablets contains

- The active substances are paracetamol and caffeine. Each tablet contains 500 mg paracetamol and 65 mg caffeine.
- The other ingredients are: sodium hydrogen carbonate, sorbitol (E420), saccharin sodium, sodium laurilsulfate, citric acid anhydrous, sodium carbonate anhydrous, povidone K25 and dimeticone 315/385.

What Solpa-Extra Soluble Tablets looks like and contents of the pack

Solpa-Extra Soluble Tablets are white bevel-edged scored effervescent tablets (score line not intended for breaking the table into equal doses), in laminate sachets.

Pack sizes: 4, 6, 12, 16, 18, 24, 30, 48 or 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Famar SA, Anthousis Av., 153 44, Pallini Attikis,
Greece.

This medicinal product is authorised in the Member States of the EEA under the following names:

Romania	Solpadeine PlusCaf 500mg/65 mg comprimate efervescente
Poland	Solpadeine Control, 500mg + 65mg effervescent tablet
Ireland	Solpa-Extra 500mg/65mg Soluble Tablets
Cyprus	Solpadeine Headache Soluble Tablets
Greece	Solpadeine™ Headache Soluble Tablets
Estonia	Solpadeine Express, 500mg/65mg kihisevad tabletid
Lithuania	Solpadeine Express 500 mg/65 mg šnypščiosios tabletės
Latvia	Solpadeine PK 500 mg/65 mg putojošas tabletes

This leaflet was last revised in December 2020