

PACKAGE LEAFLET : INFORMATION FOR THE USER

Solpa-Extra Tablets Paracetamol 500 mg Caffeine 65 mg

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take Solpa-Extra carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve within 3 days for fever and 5 days for pain.

In this leaflet:

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

1. WHAT SOLPA-EXTRA IS AND WHAT IT IS USED FOR.

Solpa-Extra contains **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever and **caffeine** which helps to increase the pain relief from paracetamol and makes you more alert. This medicine is for the symptomatic treatment of mild to moderate pain and fever in conditions such as headache, toothache and period pains.

2. BEFORE YOU TAKE SOLPA-EXTRA

Do not take Solpa-Extra if:

- You are **allergic** to paracetamol, caffeine or any of the other ingredients.
- If you are under 15 years of age or weigh less than 50kg.

DO NOT TAKE ANYTHING ELSE CONTAINING PARACETAMOL WHILE TAKING THIS MEDICINE.

Warning and precautions

Take special care with Solpa-Extra. Check with your doctor before taking this medicine:

- If you suffer from kidney or liver problems (including Gilbert's syndrome) as the dose you need to take may need to be reduced
- If you have hepatitis
- If you suffer from Glucose-6-phosphatehydrogenase enzyme deficiency,
- If you suffer from haemolytic anaemia (a form of anaemia caused by a breakdown of red blood cells)
- If you are an alcoholic or are recovering from alcoholism
- If you suffer from asthma and are sensitive to aspirin
- If you are dehydrated or suffer from chronic malnutrition
- If you have gout
- If you suffer from hyperthyroidism
- If you have arrhythmia.

Do not use Solpa-Extra without a doctor's prescription if you have alcohol problems or a liver damage and do not use Solpa-Extra and alcohol concomitantly. The effect of alcohol is not enhanced by the addition of Solpa-Extra.

Taking other medicines

Talk to your pharmacist or doctor before you take Solpa-Extra if you are taking any medication, especially:

- Clozapine (used to treat e.g. schizophrenia)
 - Beta-blockers such as atenolol, metoprolol, oxeprenolol or propranolol (used to treat high blood pressure and heart conditions)
 - Disulfiram (used in the treatment of alcoholism)
 - Fluvoxamine, monoamine oxidase inhibitors and lithium (used to treat anxiety, depression and other psychological conditions) Diazepam (used to treat anxiety or as a sedative)
 - St John's wort (used to treat mild forms of depression)
 - Phenylpropanolamine and ephedrine (decongestants) or theophylline (for asthma)
 - Other medicines containing paracetamol
 - Colestyramine (used to treat high cholesterol levels and reduce the amount of fat in the blood)
 - Metoclopramide and domperidone (used to control feeling sick or being sick).
 - Anticoagulants taken by mouth (used to prevent the blood from clotting) Dipyridamole (often used during hospital tests for heart conditions)
 - Methoxsalen (used to treat the skin condition psoriasis)
 - Carbamazepine, phenobarbitol, phenytoin, stiripentol and lamotrigine (used to treat epilepsy)
 - Levothyroxine (used to treat thyroid conditions)
 - Piperimidic acid (used to treat infections)
 - Probenecid (used to treat gout)
 - Salicylamide (used to treat fever or mild pain)
 - Isoniazid (used to treat tuberculosis)
 - Zidovudine (used to treat HIV).
 - Mexiletine (used to treat heart arrhythmias)
- Chloramphenicol, ciprofloxacin, norfloxacin, enoxacin, rifampicin (antibiotics)

The results of tests on uric acid and blood sugar may be affected by paracetamol.

Taking Solpa-Extra with food and drink:

Do not take this product with alcoholic drinks.

Solpa-Extra contains caffeine. To avoid consuming too much caffeine, you should limit drinking liquids containing caffeine (coffee, tea, cola drinks) during treatment with Solpa-Extra.

Pregnancy and Breast feeding

Talk to your doctor before taking Solpa-Extra if you are pregnant or are breastfeeding. **The caffeine in Solpa-Extra may affect your child.**

3. HOW TO TAKE SOLPA-EXTRA

Swallow the tablets whole, preferably with a drink of water.

For short term use only.

Age	Dose and how often to take
Adults, the elderly and adolescents (over 15 years) who weigh more than 60kg	Take 1-2 tablets every 4-6 hours as required. Do not take more than 6 tablets in any 24 hour period. Do not take more often than every 4 hours.
Adults, the elderly and adolescents (over 15 years) who weigh between 50kg and 60kg	Take 1 tablet every 4-6 hours as required. Do not take more than 4 tablets in any 24 hour period. Do not take more often than every 4 hours.
Do not give Solpa-Extra to children under 15 years or to adults or adolescents weighing less than 50kg.	
Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. If fever persists for more than 3 days or pain for more than 5 days or gets worse or other symptoms appear, stop taking this medicine and consult a doctor.	

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

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

If you take more Solpa-Extra 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 the medicine

You should only take this medicine as required following the dosage instructions carefully. If you forget to take a dose, take a dose as soon as you remember. **Do not** take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Solpa-Extra can sometimes have side effects, although not everybody gets them.

The following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000) and not known (cannot be estimated from available data).

Blood and lymphatic system disorders

Very rare: Thrombocytopenia (low levels of blood platelets), agranulocytosis (low levels of white blood cells)

Immune system disorders

Rare: Anaphylactic reaction, allergic dermatitis, rash, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis

Psychiatric disorders:

Common: Insomnia, restlessness, anxiety

Nervous system disorders

Common: Nervousness, dizziness, headache

Cardiac disorders

Not known: Palpitations, tachycardia (heart beating too fast)

Respiratory, thoracic and mediastinal disorders

Very rare: Bronchospasm

Gastrointestinal disorders

Common: Gastrointestinal disorder

Hepatobiliary disorders

Very rare: Hepatic function abnormal, increased transaminases (symptoms of liver damage)

General disorders and administration site conditions

Not known: Irritability

Skin and subcutaneous tissue disorders:

Very rare: serious skin reactions have been reported

When the recommended dosage is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related side effects such as nervousness, dizziness, insomnia, restlessness, anxiety, irritability, headache, gastrointestinal disorder and palpitations.

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Solpa-Extra. Your doctor will then assess the severity and decide on any further measures that may be necessary.

If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE SOLPA-EXTRA

Keep out of the sight and reach of children.

Do not store above 25°C. Keep the blister in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton, blister 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 to protect the environment.

6. FURTHER INFORMATION

What is in this medicine:

The active ingredients are: Paracetamol 500mg and Caffeine 65mg per tablet.

The other ingredients are: Maize Starch, Maize Starch, Pregelatinised, Povidone, Stearic Acid and Talc.

What this medicine looks like and contents of the pack

Solpa-Extra tablets are white, capsule-shaped, tablets.

This pack contains 10, 12, 20, 24, 30, 48 or 50 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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

Manufacturer: Wrafton Laboratories Limited, Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

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

Hungary: Paracetamol/Koffein APC 500 mg /65 mg tableta

Ireland: Solpa-Extra Tablets

Paracetamol 500 mg

Caffeine 65 mg

United Kingdom: Paracetamol & Caffeine 500mg & 65mg Tablets

This leaflet was revised in December 2022