

Package leaflet: Information for the user



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 or nurse 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 or nurse. 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 SolpaOne® Effervescent Tablets are and what they are used for
2. What you need to know before you take SolpaOne® Effervescent Tablets
3. How to take SolpaOne® Effervescent Tablets
4. Possible side effects
5. How to store SolpaOne® Effervescent Tablets
6. Contents of the pack and other information

1. What SolpaOne® Effervescent Tablets are and what they are used for

This medicine contain paracetamol, which belongs to a group of medicines called analgesics and antipyretics that relieve mild to moderate pain and fever.

It can be used to relieve headache, migraine, neuralgia, toothache, period pain, rheumatic aches and pains, sore throat and the symptoms of colds and flu.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take SolpaOne® Effervescent Tablets

Do not take SolpaOne® Effervescent Tablets

- If you are allergic to paracetamol or any of the ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking SolpaOne® Effervescent Tablets:

- If you are suffering from kidney problems
- If you are suffering from liver problems including liver problems due to excessive alcohol consumption.
- If you have Gilbert’s syndrome (mild jaundice)
- If you have hemolytic anemia (abnormal breakdown of red blood cells)
- If you are an asthmatic and sensitive to aspirin (acetylsalicylic acid).
- If you are suffering from dehydration or chronic malnutrition.
- If you are on paracetamol containing medicines
- If you have fever after paracetamol therapy
- If you suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency)

During treatment with SolpaOne® Effervescent Tablets, tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other important information

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking this medicine.

This medicine is not suitable for patients weighing less than 50 kg.

Do not use paracetamol unless prescribed by your doctor if you have an addiction to alcohol or liver damage. If this applies to you, you must not take these tablets with alcohol. If you are already taking other pain medication containing paracetamol do not take these tablets without first speaking to your doctor or a pharmacist.

Never take more SolpaOne® Effervescent Tablets than recommended. A higher dose does not increase pain relief; instead it can cause severe liver damage. The symptoms of liver damage occur first after a few days. It is important therefore that you contact your doctor as soon as possible if you have taken more SolpaOne® Effervescent Tablets than recommended in this leaflet.

Children and adolescents

Do not use SolpaOne® Effervescent Tablets in children and adolescents below 16 years of age and under 50 kg body weight.

Other medicines and SolpaOne® Effervescent Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor before you take SolpaOne® Effervescent Tablets if you are taking:

- Drugs to thin the blood (anti-coagulant drugs e.g. warfarin, other coumarins)
- Medicines used to relieve sickness (e.g. metoclopramide, domperidone)
- Medicines used to treat high cholesterol (cholestyramine)
- Probenecid (Medicine used to treat high levels of uric acid in the blood stream i.e gout)
- Medicine to treat fever or mild pain (aspirin (acetylsalicylic acid), salicylamide)
- Drugs such as rifampicin (drug that helps to fight infection) and some antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone (drugs used to treat or cure convulsions).
- Medicines used to treat epilepsy (lamotrigine)
- Medicines to treat tuberculosis (isoniazid)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol may extend the duration of action of chloramphenicol.

Effects of SolpaOne® Effervescent Tablets on laboratory tests

Uric acid and blood sugar tests may be affected.

SolpaOne® Effervescent Tablets with food and drink

There is no significant effect on absorption of Paracetamol when taken with meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

If necessary, SolpaOne® Effervescent Tablets can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol passes into breast milk. Therapeutic doses of Paracetamol can be administered during breast-feeding.

Driving and using machines

SolpaOne® Effervescent Tablets have no influence on the ability to drive and use machines.

SolpaOne® Effervescent Tablets contain sodium and aspartame

This medicine contains 533.51 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 26.68% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 10 mg aspartame in each effervescent tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take SolpaOne® Effervescent Tablets

This medicine is reserved for use in adults and in adolescents aged 16 years and above.

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

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SolpaOne® 1000 mg
effervescent tablets



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SolpaOne® 1000 mg
effervescent tablets



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Safety variation

SolpaOne® Effervescent Tablets are for oral administration and may be taken with or without food. Place the tablets in a full glass of water. Allow it to completely dissolve. Then drink the solution straight away.

If you have doubts on the correct dose of SolpaOne® Effervescent Tablets to use please consult your doctor.

Adults and adolescents (aged 16 years and above) weighing more than 50 kg
Take one [SolpaOne® 1000 mg effervescent tablet] (1000 mg paracetamol) every 6 hours as needed, up to a maximum of 4 tablets (4000 mg paracetamol) in 24 hours.

- SolpaOne® 1000 mg tablets are not suitable for:
- children and adolescents below 16 years of age
 - adults or adolescents of 16 to 18 years and weighing less than 50 kg.

If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

If complaints persist or worsen, you should seek medical advice.
Do not exceed the stated dose.

Kidney problems:
In moderate kidney problems: The usual dose is 500 mg repeated every 6 hours.
In severe kidney problems: The usual dose is 500 mg repeated every 8 hours

Liver problems:
In case of problems with your liver please consult your doctor. Your doctor may decide to reduce the dose.

In chronic alcoholics, a dose of 2000 mg per day should not be exceeded.
Do not divide the 1000 mg tablet into two equal halves for the lower doses.
Paracetamol tablets of lower strengths are available in the market.

Do not exceed the stated dose. Do not give to adolescents of 16 years of age and younger.

If you take more SolpaOne® Effervescent Tablets than you should:
Symptoms of paracetamol overdose in the first 24 hours may include paleness, nausea (feeling sick), vomiting, lack of desire to eat and stomach pain. 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 SolpaOne® Effervescent Tablets:
If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Remember to leave at least four hours between doses. Never double-up on a dose to make up for the one you have missed.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

You should stop taking SolpaOne® Effervescent Tablets and see your doctor immediately if you experience symptoms like:

- **Swelling in the face, tongue or throat, difficulty swallowing, red and itchy swellings on the skin and difficulty in breathing.**
- Serious skin reactions causing rash; or skin peeling or sores or blisters

Other side effects includes:

- Rare (may affect up to 1 in 1,000 people):**
- Bleeding problems or clotting disorders, decreased formation of cells, severe decrease in white blood cells which may lead to severe infections, frequent infections due to poorly functioning white blood cells or decrease in white blood cells, reduction in blood platelets, which increases the risk of bleeding or bruising abnormal breakdown of red blood cells, which may cause weakness or pale skin, decrease in blood count, reduced neutrophil count in blood.
 - Allergies (excluding swelling on the face, mouth, hands).
 - Depression, confusion, sensing unreal things
 - Tremor, headache
 - Abnormal vision.
 - Abnormal accumulation of fluid under the skin.
 - Stomach pain, diarrhoea, nausea, vomiting, bleeding
 - Abnormal liver function, liver failure, death of liver cells, jaundice

- Dizziness, feeling of general discomfort or uneasiness, fever, drowsiness, drug interaction.
- Overdose and poisoning.

Very rare (may affect up to 1 in 10,000 people):

- Damage caused to the liver
- Immediate severe allergic reaction (hypersensitivity reaction requiring discontinuation of treatment)
- Low levels of glucose in the blood
- Cloudy urine and kidney disorders.
- Allergic reaction of the skin
- Accumulation of fluid in the voice box
- Decrease in red blood cells
- Severe kidney impairment
- Kidney disorder
- Blood in urine
- Inability to urinate
- Uneasiness

Not Known (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow card scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store SolpaOne® Effervescent Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use SolpaOne® Effervescent Tablets after expiry date which is stated on the label after EXP. The expiry date refers to last day of that month.
- This medicinal product does not require any special temperature conditions.
- Store in the original package to protect from light and moisture.
- The solution is stable up to 8 hours below 25°C after dissolving the tablets, hence solution should be consumed within 8 hours.
- Do not use the product if you notice visible signs of deterioration, like brown or black spots, bulging of tablets or discoloration.
- Do not throw away any medicines 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. Contents of the pack and other information

What SolpaOne® Effervescent Tablet contains:

The active substance is paracetamol. Each effervescent tablet contains 1000 mg of paracetamol.

The other ingredients are: Citric acid (anhydrous) (E330), povidone, sodium bicarbonate (E500), sodium saccharin (E954), sodium carbonate (anhydrous) (E500), simeticone (E900), polysorbate 80 (E443), aspartame (E951).

What SolpaOne® effervescent tablets look like and contents of the pack:

SolpaOne® 1000mg Effervescent Tablets are white to off white coloured circular flat-faced, bevelled tablets plain on both sides. Diameter: 25.2mm

Laminate blister strips packed into cardboard cartons.

Pack size(s) for strip pack: 8, 10, 12.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Cipla (EU) Limited
Dixcart House, Addlestone Road, Bourne Business Park,
Addlestone, KT15 2LE, Surrey, United Kingdom.

Cipla

The leaflet was last approved in **February 2025.**

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