

ANVERSO (FRONT)

12 mm, 150 mm, 8 mm, 30 mm, 200 mm, 10 mm, First Bar

SOLPADEINE[®]
CAPSULES
 Paracetamol 500mg
 Codeine phosphate hemihydrate 8mg
 Caffeine 30mg

WHAT YOU SHOULD KNOW ABOUT THIS MEDICINE
 Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve after 3 days.
- 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.

IN THIS LEAFLET:

- What are Solpadeine Capsules and what are they for?
- Before you take Solpadeine Capsules
- How to take Solpadeine Capsules
- Possible side-effects
- How to store this medicine
- Further information

1. WHAT ARE SOLPADEINE CAPSULES AND WHAT ARE THEY FOR

Solpadeine Capsules can be used in patients over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

They contain paracetamol and codeine, which are both pain-relieving drugs. 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 pain killers such as paracetamol. Paracetamol also helps to reduce temperature when you have a fever. Codeine has some cough suppressant action. Caffeine is a stimulant which acts to enhance the pain-relieving effects of paracetamol.

Solpadeine Capsules provide effective relief from pain, including:

- Headache, including migraine
- Toothache
- Period pain
- Rheumatic pain
- Backache
- Neuralgia
- Relief of cold and 'flu symptoms

This product should be used only when clearly necessary.

2. BEFORE YOU TAKE SOLPADEINE CAPSULES

Do NOT take Solpadeine Capsules:

- if you are allergic to paracetamol, codeine, caffeine or any of the other ingredients listed (see Section 6).
- if you suffer from acute asthma (if you have suffered from recent asthma attacks).

if you are taking any other medicine containing paracetamol or codeine.

- 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
- if you are breastfeeding.

Take special care & tell your pharmacist or doctor before taking Solpadeine Capsules:

- if you suffer from an enlarged prostate (difficulty passing water).
- if you suffer from any bowel disorders.
- if you suffer from any liver or kidney problems.
- if you have recently had gall bladder surgery or a similar operation.

Taking Solpadeine Capsules with other medicines:

Tell your pharmacist or doctor before taking Solpadeine Capsules if you are taking any other medicines, especially:

- medicines that you have bought yourself such as cough/cold remedies and other painkillers. Many of these will contain paracetamol and/or codeine and must not be taken while you are taking Solpadeine Capsules.
- if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers (including monoamine oxidase inhibitors-MAOIs).
- medicines to help you sleep.
- medicine for high cholesterol levels or for the treatment of diarrhoea (cholestyramine).
- medicines to stop you feeling sick or vomiting (domperidone or metoclopramide).
- medicines to prevent blood clots (such as warfarin).

Taking Solpadeine Capsules with food and drink:

- You should avoid alcohol when taking Solpadeine Capsules.
- You should avoid excessive intake of caffeine containing products such as coffee, tea and some canned drinks.

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.

Children and adolescents

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.

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Pregnancy & breastfeeding:

Do not use Solpadeine Capsules during pregnancy. Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Solpadeine Capsules while you are breast-feeding. Codeine and morphine passes into breast milk.

Driving & using machines:

Solpadeine Capsules may make you feel drowsy. You should not drive or operate machinery until you know how they affect you.

3. HOW TO TAKE SOLPADEINE CAPSULES

How many capsules should I take & how often?

Swallow Solpadeine Capsules with water.

Adults, including the elderly, and children aged 12 years and over:

- Take 2 capsules every 4 hours as required.
- Do not take more often than every 4 hours.
- Do not take more than 8 capsules in 24 hours.**
- This product should be used only when clearly necessary.

Solpadeine Capsules should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Do not exceed the stated dose.

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.

Prolonged use except under medical supervision may be harmful.

What should I do if I forget to take a dose?

Do NOT take a double dose to make up for a forgotten dose. You must allow at least 4 hours between doses.

WHAT SHOULD YOU DO IF YOU TAKE TOO MANY SOLPADEINE CAPSULES?

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 have any questions about this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

This medicine may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down. You may also become constipated. You may experience problems with your blood which means that you may bleed or bruise easily (known as thrombocytopenia) or which makes it more likely that you may get an infection (known as agranulocytosis).

If you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting, or if you have previously experienced breathing problems with aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product, stop taking this medicine and tell your doctor immediately.

Taking any type of pain reliever for headaches for a long period of time can make them worse. If this situation is experienced or suspected, stop taking this medicine and talk to your doctor.

Very rarely, some of the following side effects may occur:

- allergic reactions such as skin rash or itching, sometimes with breathing problems, or swelling of the lips, tongue, throat or face.
- skin rash or peeling of the skin which may be accompanied by mouth ulcers.

These effects go away once you stop taking the medicine. If any of these effects occur, or get serious, or if you notice any other side effect not listed in this leaflet, stop taking this medicine, and tell your doctor or pharmacist immediately.

This product contains codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

5. HOW TO STORE THIS MEDICINE

- Keep out of the reach and sight of children.**
- Do not take this medicine after the expiry date (EXP) which is stated on the outer carton and blisters. The expiry date refers to the last day of that month.
- Do not store this medicine above 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Solpadeine Capsules contain:

Solpadeine Capsules contain paracetamol 500mg, codeine phosphate hemihydrate 8mg and caffeine 30mg.

The capsules also contain maize starch, magnesium stearate, titanium dioxide (E171), erythrosine (E127), patent blue (E131), quinoline yellow (E104), gelatin, shellac, propylene glycol, black iron oxide (E172).

What Solpadeine Capsules look like and contents of the pack:

Solpadeine Capsules are gelatin capsules with a red, opaque cap and a white, opaque body with 'SOLPADEINE' printed in black or plain on both the sides. They are available in packs of 6, 12, 24, 32, 36, 48, 60, 72 or 96 capsules. Not all may be marked.

Product Authorisation holder and manufacturer:

The Product authorisation holder is:
 Chefaro Ireland Limited, First Floor, Block A, The Crescent Building, Northwood Office Park, Dublin 9 and all enquiries should be sent to this address.

The manufacturer is:
 SmithKline Beecham S.A., Carretera de Aljovar, km 2500 Alcala de Henares, Madrid, Spain or Swiss Caps GmbH, Grassingerstraße 9, 83043 Bad Aibling, Germany (Aenova Group).

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