

Other nervous system problems which can cause:

- dizziness, light headedness, disorientation and drowsiness
- headache, tremor, nervousness, confusion, irritability, restlessness, anxiety and mood changes
- vertigo.

Heart and circulation effects which can cause:

- an increased awareness of your heart beat
- a head rush or dizzy spells
- an increase in your heart rate or sweating.

Other less serious side effects

which can cause:

- difficulty in passing water, needing to pass urine more often, or passing less urine than usual
- decreased libido or potency
- muscle rigidity
- a dry mouth
- your eye's pupil may become smaller
- blurred or double vision
- nightmares.

How do I know if I am addicted?

If you take the 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 if 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

How to store your medicine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the pack. Do not store above 25°C. Store in the original packaging.

Contents of the pack and other information

What this medicine contains

Each film-coated white capsule-shaped tablet, debossed on one side with "PCC", contains the active ingredients: paracetamol 500 mg, caffeine 30 mg and codeine phosphate 8 mg.

They also contain: povidone, maize starch, methylcellulose, talc, purified water, calcium stearate, methylhydroxypropylcellulose and polyethylene glycol.

This product is available in pack sizes of 30 and 10 tablets.

The Marketing Authorisation holder and manufacturer is Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK. Distributor: Phoenix Labs Unlimited Company, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland.

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Package leaflet: Information for the patient

Syndol® Headache Relief Tablets

Paracetamol, Codeine, Caffeine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **For the short term treatment of acute moderate pain, which is not relieved by paracetamol, ibuprofen or aspirin alone.**
- **You should only take this product for a maximum of three days at a time. If you need to take it for longer than three 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 three 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 three days it can make them worse.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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. 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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

What this medicine is and what it is used for

This medicine contains:

- **codeine phosphate.** Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.
- **paracetamol,** another analgesic to relieve pain.
- **caffeine** which helps to increase the pain relief from paracetamol and makes you more alert.

These tablets are for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. This medicine is for the relief of migraine, headache, rheumatic pain, period pain, toothache and nerve pain.

What you need to know before you take this medicine

This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

If you take a painkiller for headaches for more than three days it can make them worse.

Do not take this medicine if you:

- are **allergic** to paracetamol, codeine, caffeine or any of the other ingredients of this medicine (listed in section 6)
- have acute asthma
- have severe respiratory disease
- suffer from alcoholism
- have had recent bile duct surgery (e.g. gall stones)
- suffer from paralytic ileus, where your bowel has ceased to function
- have recently had a head injury or raised pressure in the skull
- are breastfeeding
- have been told by your doctor that you are a CYP2D6 ultra metaboliser
- are under 18 years and have had your tonsils or adenoids removed.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine, if you

- suffer from kidney or liver problems, including alcoholic liver disease
- have an enlarged prostate gland
- suffer from low blood pressure
- suffer from inflammatory or obstructive bowel disorders such as constipation, diarrhoea or bloating
- suffer from an underactive thyroid gland
- are elderly or debilitated
- have a condition called myasthenia gravis which weakens the muscles
- 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.

Other medicines and Syndol®

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

- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin. Aspirin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- cimetidine, a medicine to treat heartburn or peptic ulcers
- tricyclic antidepressants, which are medicines used to treat depression e.g. amitriptyline and imipramine
- antipsychotic medicines used to treat mental illness e.g. chlorpromazine and mocllobemide
- quinidine or mexiletine, used to treat heart problems
- antidepressant drugs called monoamine oxidase inhibitors (MAOI's) - these are medicines such as phenelzine and moclobemide
- the antibiotic chloramphenicol
- other CNS depressant drugs such as

sodium oxybate

- barbiturates and benzodiazepines which are medicines to calm you down or to help you sleep (e.g. mephobarbital, pentobarbital, diazepam and alprazolam).
- medicines for diarrhoea and tummy cramps as taking these at the same time as Syndol Headache Relief Tablets may make you constipated.
- medicines such as atropine, procyclidine, or hyoscine which are used to treat problems with gut movement. Taking these at the same time as Syndol Headache Relief Tablets may make you severely constipated and may make it difficult for you to pass urine.
- some antihistamines which may be used in cough/cold remedies and anti-allergy products. Taking these at the same time as paracetamol, caffeine and codeine tablets may make you severely constipated and may make it difficult for you to pass urine.
- naltrexone – used in the treatment of drug dependence.
- 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.

Taking this medicine with food, drink and alcohol

Do not drink alcohol (beer, wine, spirits etc) while taking this product.

Pregnancy and breastfeeding

Do not take this medicine if you are breastfeeding.

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

Driving and using machines

These tablets might cause drowsiness. If you are affected, do not **drive or operate machinery**.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you
- It may be an offence to drive when taking this medicine
- However, you would not be committing an offence if:
 - The medicine has been taken to treat a medical or dental problem and
 - You have taken it according to the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>

How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults

Take 2 tablets every 4-6 hours as required. Do not take more than 8 tablets in 24 hours.

Children aged 16-18 years

Take 1-2 tablets every 6 hours as required. Do not take more than 8 tablets in 24 hours.

Children aged 12-15 years

Take 1 tablet every 6 hours, as required. Do not take more than 4 tablets in 24 hours.

Do not take more frequently than every 6 hours.

Do not give to children under 12 years.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Do not use for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.

Codeine addiction

This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

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. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

Possible Side Effects

Some people may have side-effects when taking this medicine. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

STOP TAKING the tablets and contact your doctor immediately if you develop any of the following serious side effects at any time while taking your medicine:

Allergic reactions:

The following symptoms may mean you are having an allergic reaction to this medicine:

- rash, itching, swollen red areas of the skin or swelling of the face
- very rare cases of serious skin reactions have been reported

Blood disorders which can cause:

- unexplained or unusual bruising or bleeding
- fever and infections.

Heart and circulation effects which can cause:

- an unusually low heart rate
- low blood pressure
- hypothermia

Nervous system problems which can cause:

- hallucinations.

Other serious side effects which can cause:

- restricted breathing
- abdominal or back pain.

Less serious side effects, that may occur include those listed below:

Stomach and intestine effects

including:

- constipation, stomach cramps, feeling sick and vomiting.