

Package leaflet: Information for the user**Syndol® Tablets**

Paracetamol, Codeine Phosphate,
Doxylamine Succinate and Caffeine

Is this leaflet hard to see or read?

Phone +353-1-5742410 for help

Important things you should know about Syndol

- **This medicine can only be used for the short term treatment of acute moderate pain when other painkillers have not worked**
- **You should only take this product for a maximum of 3 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 3 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 3 days it can make them worse**

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

Always use 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.
- If you have any further questions, ask your doctor or pharmacist.
- 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).

What is in this leaflet:

1. What Syndol is and what it is used for
2. What you need to know before you take Syndol
3. How to take Syndol
4. Possible side effects
5. How to store Syndol
6. Contents of the pack and other information

1. WHAT SYNDOL IS AND WHAT IT IS USED FOR

The name of your medicine is Syndol Film-coated Tablets (called Syndol throughout this leaflet).

Syndol contains four different medicines called caffeine, codeine phosphate, doxylamine succinate and paracetamol. Paracetamol acts as an analgesic (painkiller) and an antipyretic (lowers body temperature), codeine phosphate is an analgesic, doxylamine succinate is an antihistamine and caffeine is a mild stimulant.

Syndol is used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen and aspirin alone such as headache, including muscle contraction or tension headache, migraine, neuralgia, period pain, toothache and other dental pain, muscular and rheumatic aches and pains and for pain relief following surgery or dental procedures.

Codeine can be used in children 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 but not if they are under 18 years of age and have had their tonsils or adenoids removed due to Obstructive Sleep Apnoea Syndrome.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SYNDOL

- **This medicine contains codeine which can cause addiction if you take it continuously for more than 3 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 3 days it can make them worse**

Do not take Syndol if

- you are allergic to codeine, paracetamol, doxylamine succinate, caffeine or any of the ingredients of this medicine (listed in section 6). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- you are having an asthma attack or have severe breathing problems
- you have recently had a head injury
- you have been told by your doctor that you have increased pressure in your head. Signs of this include headaches, being sick (vomiting) and blurred eyesight
- you have recently had an operation on your liver, gall bladder or bile duct (biliary tract)
- you are at risk of blocked intestine (paralytic ileus)
- you are taking other medicines containing codeine or any other paracetamol-containing products
- you are taking a medicine of the class known as Monoamine Oxidase Inhibitors (MAOIs, e.g. selegiline, moclobemide), which are used as antidepressants, or if you had taken any medicine of this group in the past 14 days.
- you are an alcoholic
- the person going to take the tablets is under 12 years of age
- you are under 18 years of age and have had your tonsils or adenoids removed due to Obstructive Sleep Apnoea Syndrome
- you know that you metabolise very rapidly codeine into morphine
- you are breast-feeding or planning to breastfeed

Do not take Syndol if any of the above apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Syndol if:

- You have liver, kidney, thyroid or heart problems and/or are elderly or of a weakened state;
- You have high blood pressure, problems with the prostate gland, obstructive bowel problems, acute abdominal conditions (e.g. peptic ulcer), hormonal problems, problems passing urine or have had recent gastrointestinal surgery;
- You are in shock, have gallstones, glaucoma, or a disease called myasthenia gravis (a condition which weakens muscles) or a history of fits;
- You have a history of mood swings, alcohol or drug abuse or are under psychiatric treatment;
- You are taking a benzodiazepine (used for treatment of anxiety or sleep disorders), e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam

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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Syndol

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Syndol can affect the way some other medicines work. Also, some other medicines can affect the way Syndol works.

While taking Syndol you should not take any other medicines which contain paracetamol.

This includes some painkillers, cough and cold remedies. It also includes a wide range of medicines available from your doctor and more widely in shops.

Do not take this medicine and tell your doctor or pharmacist if you are taking

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have recently taken them in the last two weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine.

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, antipsychotics, tricyclic antidepressants and phenothiazines) or a benzodiazepine used to treat anxiety or sleep disorders
- Medicines for the treatment of high blood pressure (diuretics and antihypertensives)
- Medicines to treat or prevent clinical depression (antidepressants)
- Medicines used to treat mental distress or disorder (antipsychotics)
- Any of the group called antimuscarinics (e.g. atropine, hyoscine)
- Any of the group called neuromuscular blockers (e.g. tubocurarine)
- Medicines used to thin the blood such as warfarin (or other coumarins)
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels
- Hydroxyzine - to treat anxiety and tension
- Mexiletine - to treat irregular heartbeat
- Kaolin or loperamide - for the treatment of diarrhoea
- Naloxone - to treat a narcotic overdose
- Naltrexone - used as part of a treatment program for drug or alcohol dependence
- Cimetidine - to treat stomach ulcers
- Cisapride - to treat gastro-oesophageal reflux disease
- Quinidine - to treat irregular heart rate
- The oral contraceptive pill

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Syndol.

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, you should only take these together if prescribed by a doctor. Please follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Taking Syndol with food and drink

Avoid alcohol whilst taking Syndol.

Children and adolescentsUse 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.

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 this medicine.

Do not take Syndol and speak to your doctor if

- you are in the last three months of pregnancy
- in labour
- you are breast-feeding. Codeine and morphine passes into the breast milk.

Driving and using machines

Syndol 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 is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in 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

Syndol contains lactose, sunset yellow (E110), quinoline yellow (E104) and sodium

- This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking this product.
- It also contains sunset yellow (E110) and quinoline yellow (E104) which may cause allergic reactions
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE SYNDOL

Always take Syndol exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

- Do not take Syndol 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.
- 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.

Adults, including the elderly

- Take one or two tablets every four to six hours as needed for relief
- Adults should wait at least 4 hours before taking another dose
- Do not take more than eight tablets in a 24 hour period
- Do not exceed the stated dose

If you are elderly or of a weakened state you should seek advice from your doctor before taking Syndol as dosage adjustment may be required.

Children aged 16 to 18 years

1 to 2 tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours

Children aged 12 to 15 years

1 tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours

Children under 12 years

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

If you take more Syndol than you should

- Signs of overdose may include unusually pale skin, nausea, vomiting, loss of appetite, abdominal pain, pupils that may be pin-point in size, difficulty in breathing, an increased or irregular heart rate, and loin (kidney) 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.
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

If you have forgotten to take Syndol

If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

If you stop taking Syndol

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Syndol and see a doctor or go to a hospital straight away if:

- You have a rash, fever, swelling, bruising or tiredness
- You have difficulty in breathing or you feel dizzy

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing
You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction**
- You get serious skin reactions. Very rare cases have been reported.

Talk to your doctor straight away if you notice the following serious side effects:

- Severe stomach pain, which may reach to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis or thrombocytopenia)
- Yellowing of the skin or the whites of the eyes

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- Feeling sick (nausea)
- Being sick (vomiting)
- Low blood pressure (causing light-headedness or fainting when standing up)
- Confusion
- Depression
- Difficulties sleeping
- Shaking, fits
- Irregular heart beat
- Stomach pain
- Sweating
- Facial flushing
- General discomfort
- Loss of appetite
- Very slow or shallow breathing
- Shortness of breath
- Hallucinations, nightmares
- Cramps or stiffness
- Becoming dependent on codeine

Other effects that may occur are; constipation, headache, drowsiness, dizziness, restlessness, difficulties passing urine, dry mouth, blurred vision, diarrhoea, thick phlegm.

How do I know if I'm 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE SYNDOL

- Keep out of the sight and reach of children.
- Do not use after the expiry date shown on the details of packaging. The expiry date refers to the last date of that month.
- Store below 25°C in the original packaging to protect from moisture.
- Do not throw away medicines via 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 Syndol tablets contain

- Each Syndol tablet contains the following active ingredients, 450mg of paracetamol, 10mg of codeine phosphate, 5mg of doxylamine succinate and 30mg of caffeine.
- They also contain povidone, croscarmellose sodium, pregelatinised maize starch, magnesium stearate, talc and water. The tablet film coating contains lactose monohydrate, hypromellose, titanium dioxide, polyethylene glycol 4000; quinoline yellow (E104) and sunset yellow (E110).

What Syndol tablets look like and contents of the pack

Syndol are yellow film-coated capsule shaped tablets. Each tablet has 'Syndol' embossed on one side, and the other side is scored with a break line. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. They are in blister strips packed into cartons of 10 and 30 tablets.

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