

## **Syndol Film Coated Tablets**

paracetamol, 450mg  
codeine phosphate hemihydrate, 10mg  
doxylamine succinate, 5mg  
caffeine, 30mg

### **PATIENT INFORMATION LEAFLET**

- Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yourself you get any side effects, talk to your doctor or pharmacist. This includes any 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**
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- 3. How to take Syndol Tablets**
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#### **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 paracetamol, codeine, doxylamine succinate and caffeine.

Syndol is indicated for the short-term relief of tension headache and other pains of a similar tension state origin, or pain following surgery or a dental procedure.

This product contains codeine. 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. 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.

#### **2. What you need to know before you take Syndol**

##### **Important information you should know about Syndol.**

- **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 using it.

- **If you take this medicine for headaches for more than three days** it can make them worse. If you need to take for longer than three days, you should see your doctor or pharmacist for advice.

**Do not take Syndol if:**

- You are allergic to any of the ingredients in this medicine (listed in Section 6 'Contents of the pack and other information').
- 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
- You know that you metabolise codeine into morphine very rapidly.
- You are due to give birth soon
- You are breast feeding
- You have asthma or 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 headache, being sick (vomiting) and blurred eyesight
- You have recently had gall bladder surgery or a similar operation
- You have severe liver disease
- You are an alcoholic or have recently consumed a large amount of alcohol
- You are taking monoamine oxidase inhibitors (used to treat depression) or have recently taken them within the last 14 days
- You are under 12 years of age
- You are sensitive to aspirin or other medicines used for the treatment of inflammation (Non-Steroidal Anti-Inflammatory Drugs) such as Ibuprofen

**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

You should not take Syndol if you are sensitive to aspirin or other medicines used for the treatment of inflammation (Non-Steroidal Anti-inflammatory Drugs) such as Ibuprofen.

**Talk to your doctor or pharmacist before taking Syndol if:**

- You have a stomach ulcer or have kidney or thyroid problems, having trouble passing water, glaucoma or you are elderly or debilitated
- You have high blood pressure, a problem with the prostate gland or adrenal glands
- You have low blood pressure (hypotension)
- You suffer with your bowels (e.g. constipation, pain) or recently had bowel surgery.
- You have gallstones, liver disease, are in shock, have a condition which weakens the muscles (myasthenia gravis), history of being depressed, suffer from anxiety, have irregular heartbeats or fits (convulsions).
- You have a history of mood swings (emotional instability)
- You have a history of drug or alcohol abuse or dependence
- You suffer from an enzyme deficiency called Glucose-6-phosphate-dehydrogenase deficiency
- You suffer from Gilbert's syndrome where your blood contains elevated levels of a substance called bilirubin - You suffer from respiratory problems such as emphysema
- You suffer from kyphoscoliosis, a condition where there is curvature of the spine
- You are severely overweight (obesity)

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

**Take special care**

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

If you need to use this product for more than three days at a time, see your doctor, pharmacist or healthcare professional.

Syndol tablets should not be taken continuously over prolonged periods in the maximum dose.

Other products containing paracetamol/ codeine should not be taken at the same time as Syndol.

Excessive caffeine intake should be avoided when taking Syndol.

Taking codeine regularly for a long time can lead to addiction, which might cause

you to feel restless and irritable when you stop taking the tablets.

Avoid alcohol while taking Syndol.

### **Taking other medicines**

Please 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 medicines work. Also, some medicines can affect the way Syndol works.

While taking Syndol you should not take any other medicines which contain codeine or paracetamol. This includes some painkillers, cough and cold remedies.

### **Tell your doctor if you are taking any of the following medicines:**

- Medicines which make you drowsy or sleepy (CNS depressants) (e.g barbiturates, anaesthetics, hypnotics, other opioid analgesics including methadone, anxiolytic sedatives such as hydroxyzine, antipsychotics, tricyclic antidepressants and phenothiazines)
- Medicines known as antimuscarinics such as atropine
- Medicines for the treatment of high blood pressure (diuretics and antihypertensives)
- Medicines used to treat irregular heartbeat (mexiletine, quinidine)
- Medicines used to treat or prevent clinical depression (antidepressants)
- Medicines used to treat mental distress or disorder (antipsychotics)
- Medicines used to treat anxiety (benzodiazepines) due to an increased risk of sedation, breathing difficulties or even coma when both are taken together
- Medicines used to treat hyperparathyroidism (cinacalcet)
- Medicines used to thin the blood such as warfarin
- Chloramphenicol, flucloxacillin or rifampin, antibiotics used to treat infections
- Medicines used to stop you feeling sick (nausea) or being sick (vomiting) such as metoclopramide or domperidone
- Medicines for lowering blood cholesterol levels such as colestamine
- Medicines used to treat allergies (antihistamines)
- Medicines used to treat diarrhoea such as loperamide or kaolin
- Medicines used to treat stomach ulcers (cimetidine)
- Medicines used to treat gastro-oesophageal reflux disease (cisapride)
- Medicines used to treat alcohol or drug dependence (disulfiram, naltrexone)
- Oral contraceptives ('the pill')

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

### **Taking Syndol with food and drink**

You should not drink alcohol while you are taking Syndol. This is due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.

### **Driving and using machines**

Syndol may affect your ability to drive or operate machinery as it may cause drowsiness. Do not drive or use machinery if you feel drowsy or dizzy after taking this medicine.

### **Children and adolescents**

Children 12 to 18 years of age who have breathing problems should not take this product. This includes breathing problems while sleeping or other lung problems.

#### 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.

### **Pregnancy and breast-feeding**

Syndol is not recommended for use during pregnancy. Do not take Syndol while you are breastfeeding. Codeine and morphine passes into breast milk.

### **Important information about some of the ingredients**

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.

It also contains sunset yellow (E11 0) which may cause allergic reactions.

## **3. How to take Syndol Tablets**

### **Adults:**

- Take one or two tablets every four or six hours as needed for relief.
- Do not take more than 8 tablets in a 24 hour period
- Do not exceed the stated dose
- Do not take for more than 3 days. If symptoms persist or become worse or do not improve after 3 days, talk to your doctor for advice.

### **Elderly:**

This product should be taken with caution as may affect their breathing. Ask your pharmacist for advice.

### **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 years, due to the risk of severe breathing problems.

**Possible withdrawal effects**

This medicine contains codeine which 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 are suffering from withdrawal symptoms.

**If you take more Syndol than you should**

Tell your doctor straight away or go to your nearest hospital casualty-department, even if you feel well. This is because of the risk of delayed serious liver damage. Take the pack with you so that the doctor knows what you have taken.

**If you forget 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 two doses at, or, near the same time. Remember to leave at least 4-6 hours between doses.

**4. Possible side effects**

**Like all medicines, Syndol can cause side effects, although not everybody gets them.**

**Stop taking Syndol and see a doctor straight away if you get any of the following side effects:**

- You get swelling of the hands, feet, ankles, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). You may be having an allergic reaction to the medicine.

**Tell your doctor straight away if you notice any of the following side effects:**

- You have rash, fever, swelling, bruising or tiredness
- You develop yellowing of the skin or the whites of the eyes
- You have severe abdominal pain which may reach to your back. This could be a sign of inflammation of the pancreas (acute pancreatitis)
- You get infections or bruise more easily. This could be because of a blood problem.
- You experience blistering or bleeding of the skin around the lips, eyes, mouth, nose

and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.

- You have a severe blistering rash where layers of the skin may peel off to leave large areas of raw-exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolysis'. Very rare cases of serious skin reactions have been reported.

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

- Constipation
- Headache
- Drowsiness, fatigue
- Dizziness
- Restlessness
- Twitching or tightening of muscles
- Difficulty or pain passing urine
- Dry mouth
- Blurred or double vision/visual disturbances
- Ringing in ears (tinnitus)
- Feeling or being sick
- Diarrhoea
- Thick phlegm
- Low blood pressure (causing light headedness or fainting when standing up)
- Confusion
- Depression/mood swings
- Difficulty sleeping,
- Shaking/fits
- Irregular heartbeat
- Palpitations
- Stomach pain
- Sweating
- Facial flushing
- General discomfort
- Loss of appetite (anorexia)
- Very slow or shallow breathing, shortness of breath
- Hallucinations, nightmares
- Cramps or stiffness
- Codeine dependence
- Not being able to pass water (urinary retention)

Prolonged use can lead to worsening of headaches. If you feel you are reacting badly to this medicine in any way stop taking the tablets and tell your doctor or

pharmacist.

### **How do I know if I'm addicted?**

If you take this 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 take more than the recommended dose.
- When you stop taking the medicine you still 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)  
By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Syndol tablets**

Keep this medicine out of the sight and reach of children. No special storage precautions Do not use after the expiry date which is stated on the carton 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 protect the environment.

### **6. Contents of the pack and other information**

#### **What Syndol contains**

Each Syndol film coated tablet contains 450mg of paracetamol, 10mg of codeine phosphate hemihydrate, 5mg of doxylamine succinate and 30mg of caffeine. Paracetamol and codeine phosphate act as analgesics (painkillers), doxylamine succinate is an antihistamine and caffeine is a mild stimulant. It also contains the excipients maize starch, croscarmellose sodium, povidone, talc, magnesium stearate, Opadry II yellow, (lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000, quinolone yellow (E104), FD & C yellow/sunset yellow (E110).

#### **What Syndol 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. They are available in blister strips packed into cartons of 10, 20, 24 and 50 tablets. Not all



pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

sanofi-aventis Ireland Ltd., T/A SANOFI  
Citywest Business Campus  
Dublin 24.

**Manufacturer**

SSL International,  
Peterlee, SR8 2RU,  
United Kingdom.

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