Package leaflet: Information for the user
Syndol Tablets
Paracetamol, Codeine Phosphate, Dicyclomine Hydrochloride, Doxylamine Succinate and Caffeine
in this leaflet hard to see or read?
Phone 0643372101 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 has 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. How to take Syndol
3. Possible side effects
4. How to store Syndol
5. Contents of the pack and other information

The name of your medicine is Syndol Film-coated Tablets (called Syndol throughout this leaflet).
Syndol contains four different medicines called caffeine, codeine phosphate, dicyclomine hydrochloride and codeine.

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 or other pain, muscular and rheumatic aches and pains and for pain relief following surgery or dental procedures.

Caffeine 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.

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, dicyclomine hydrochloride, 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 had your tonsils or adenoids removed due to Obstructive Sleep Apnoea Syndrome
you are breast-feeding or planning to breastfeed
you have high blood pressure, problems with the prostate gland, obstructive bowel problems, acute abdominal conditions (e.g. pericolic ulcer), hormonal problems, problems passing urine or have had recent gastrointestinal surgery
you are in shock, have gallstones, gynaecoma 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 monoamine oxidase inhibitor (MAOI) (used for the treatment of anxiety or sleep disorders), e.g. dapoxetine, clomipramine, bupropion (e.g. atomoxetine), citalopram, escitalopram, fluoxetine, fluvoxamine, mirtazapine, paroxetine, venlafaxine or trazodone, or a history of major depression

Do not take Syndol if
you are under 12 years of age
you have recently had an operation on your liver, gall bladder or bile duct (biliary tract)
you have recently had a head injury
you are allergic to codeine, paracetamol, doxylamine succinate, caffeine, or any of the ingredients of this medicine
you have a history of mood swings, alcohol or drug abuse or are under psychiatric treatment
you are under 18 years of age
you are at risk of blocked intestine (paralytic ileus)
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 are having an asthma attack or have severe breathing problems
you are allergic to codeine, paracetamol, doxylamine succinate, caffeine, or any of the ingredients of this medicine
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you are having an asthma attack or have severe breathing problems
you are allergic to codeine, paracetamol, doxylamine succinate, caffeine, or any of the ingredients of this medicine
you have a history of mood swings, alcohol or drug abuse or are under psychiatric treatment
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you are having an asthma attack or have severe breathing problems
you are allergic to codeine, paracetamol, doxylamine succinate, caffeine, or any of the ingredients of this medicine
you have a history of mood swings, alcohol or drug abuse or are under psychiatric treatment
you are under 18 years of age

Warnings and precautions
Tell your doctor or pharmacist before taking Syndol F:
• 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. pericolic ulcer), hormonal problems, problems passing urine or have had recent gastrointestinal surgery
• you are in shock, have gallstones, gynaecoma 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 monoamine oxidase inhibitor (MAOI) (used for the treatment of anxiety or sleep disorders), e.g. dapoxetine, clomipramine, bupropion (e.g. atomoxetine), citalopram, escitalopram, fluoxetine, fluvoxamine, mirtazapine, paroxetine, venlafaxine or trazodone, or a history of major depression

You should not take Syndol if
• you are under 12 years of age
• you have high blood pressure, problems with the prostate gland, obstructive bowel problems, acute abdominal conditions (e.g. pericolic ulcer), hormonal problems, problems passing urine or have had recent gastrointestinal surgery
• you are in shock, have gallstones, gynaecoma 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 monoamine oxidase inhibitor (MAOI) (used for the treatment of anxiety or sleep disorders), e.g. dapoxetine, clomipramine, bupropion (e.g. atomoxetine), citalopram, escitalopram, fluoxetine, fluvoxamine, mirtazapine, paroxetine, venlafaxine or trazodone, or a history of major depression

Syndol is used for the short term treatment of acute moderate pain which is not relieved by other painkillers such as paracetamol or ibuprofen alone but not if they are under 18 years of age
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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

Do not take this medicine and tell your doctor or pharmacist if you are taking
• Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anabolic androgens, antipsychotics, antidepressants and phenoxybenzamine) or a benzodiazepine used to treat anxiety or sleep disorders
• Medicines for the treatment of high blood pressure (diuretics and alphaagonists)
• Medicines to treat or prevent clinical depression (antidepressants) or to treat bipolar disorders (antipsychotics)
• Any of the group called antimuscarinics (e.g. atropine, hyoscyamine)
• Any of the group called neurmuscular 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)
• Colestipol - for lowering blood cholesterol levels
• Hydroxyzine - to treat anxiety and tension
• Maxelone - to treat irregular heartbeat
• Katrin or spironolactone - for treatment of diarrhoea
• Naltrexone - to treat a narcotic overdose
• Naloxone - used as part of a treatment program for drug or alcohol dependence
• Oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam, tempeclam proxetine and other antipsychotics or neuroleptics
• Medicines used to treat mental distress or disorder (antipsychotics)
• Medicines to treat or prevent clinical depression (antidepressants)
• Medicines to treat epilepsy (e.g. phenytoin, carbamazepine)
• Medicines to control diabetes (e.g. metformin)
• Medicines used to treat mental distress or disorder (antipsychotics)
• Medicines to treat moderate or severe pain, such as: aspirin, paracetamol, ibuprofen
• Medicines used to treat nausea (e.g. prochlorperazine, domperidone, metoclopramide)
• Medicines used to treat moderate or severe pain, such as: aspirin, paracetamol, ibuprofen
• Medicines used to treat nausea (e.g. prochlorperazine, domperidone, metoclopramide)
• Medicines used to treat brain disorders, such as: aspirin, paracetamol, ibuprofen
• Medicines used to treat brain disorders, such as: aspirin, paracetamol, ibuprofen
• Medicines used to treat nausea (e.g. prochlorperazine, domperidone, metoclopramide)

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

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 adolescents
Use in children and adolescents after surgery
Children 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
Caffeine 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
• you have an intolerance to some sugars, speak to your doctor
• you are sleeping poorly
• 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 unless 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 this 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), and quinoline yellow (E104)
• 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 can cause allergic reactions.

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 these 3 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 3 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 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, a dry mouth, blurred vision, diarrhoea, high blood pressure, delirium, cramps or diarrhoea. Becoming dependent on codeine.

Other effects that may occur are;
• Constipation, headache, drowsiness, dryness, restlessness, difficulties passing urine, dry mouth, blurred vision, diarrhoea, high blood pressure.

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.

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.
• 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 medicine you no longer use. These measures will help protect the environment.

Contents of the pack and other information
What Syndol tablets contain
• Each Syndol tablet contains the following active ingredients, 460mg of paracetamol, 10mg of codeine phosphate, 5mg of doxylamine succinate and 33mg of caffeine.

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 so the doctor knows what you have taken.

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
• you are sleeping poorly
• 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 unless 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 this 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.

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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, a difficulty in breathing, an increased or irregular heart rate, and loin (renal) 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 serious, 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.

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.