

PATIENT INFORMATION LEAFLET

Syndol® Tablets

(paracetamol/codeine phosphate hemihydrate/
doxylamine succinate/caffeine)

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

- Keep this leaflet, you may wish to read it again.
- Ask your doctor or 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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

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. You should only take the 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.

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 three days. This can give you withdrawal symptoms from the medicine when you stop using it. **If you take a painkiller for headaches for more than three days it can make them worse.**

Do not take:

- If you are allergic to paracetamol, codeine phosphate hemihydrate, doxylamine succinate or caffeine or to any of the ingredients in this product, or opiod analgesics. See section 6 - 'Contents of the pack and other information' for the full list of ingredients.
- At the same time as taking other medicines containing paracetamol, codeine or Monoamine inhibitors (MAOIs) or within 14 days of stopping treatment with MAOIs.
- If you are a breast-feeding mother, except on the advice of your doctor.

Warnings and precautions

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 infirm.
- If you have high blood pressure, a problem with the prostate gland or adrenal glands, if you suffer with your bowels (e.g. constipation, pain) or recently had bowel surgery.
- If you have gallstones, liver disease, are in shock, have a condition which weakens the muscles, history of being depressed, irregular heart beats or fits (convulsions).
- If you have a history of mood swings (emotional instability) or alcohol or drug abuse.
- Syndol can effect the results of blood tests.

Other medicines and Syndol

- Speak to your pharmacist if you are taking warfarin, cholestyramine, domperidone, guaifenesin, hydroxyzine, mexiletine, metoclopramide, cisapride, naloxone, nalatraxone, drugs known as central nervous system depressants, phenobarbitone, anaesthetics, pethidines, hypnotics, sedatives, antidepressants, monooxidase inhibitor, cimetidine, disulfiram, oral contraceptives, diuretics, opiod analgesics, antidiarrhoeal (loperamide) and antiperistaltics (kaolin), potassium iodine, drugs to lower blood pressure, quinidine or any medicine containing paracetamol or codeine.

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 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.
- 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.
- Taking a painkiller for headaches too often for too long can make them worse.
- Avoid alcohol while taking Syndol.

Driving and using machines

- Syndol may cause drowsiness. If affected do not drive or operate machinery.

If you are pregnant or breast-feeding

- Syndol is not recommended for use during pregnancy or whilst breast-feeding.

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 aluminium lake (E110) which may cause allergic reactions.

3. How to take Syndol

Adults and children over 12 years:

- Take one or two tablets every four or six hours as needed for relief.
- Do not take for more than three days.
- If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.
- Do not take more than eight tablets in a 24 hour period.
- Do not exceed the stated dose.
- If symptoms persist or become worse, consult your doctor.

Children under 12 years:

Not recommended for children under 12 years.

Elderly:

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

Patients with kidney and liver problems:

Take Syndol only as recommended by your doctor.

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 too many of the tablets:

Speak to your doctor immediately, even if you feel well, because of the risk of delayed serious liver damage.

4. Possible side-effects

As with all medicines, these tablets can have side-effects:

- If you get any of the following side-effects, stop taking Syndol and see a doctor immediately, as you may be allergic to this product: rash, fever, swelling, difficulty breathing or swallowing.
- Severe abdominal pain which may be due to inflammation of the pancreas (acute pancreatitis).
- You may bruise or get tired easily, due to changes in your blood cells. You are also at an increased risk of infection.
- Other effects that may occur are: constipation, headache, drowsiness, dizziness, restlessness, twitching of muscles, difficulties or pain passing urine, dry mouth, blurred or double vision, visual disturbances, ringing in ears, feeling or being sick, diarrhoea, thick phlegm.
- These effects may occur but less frequently: low blood pressure (causing lightheadedness or fainting when standing up), confusion, depression, mood swings, difficulties sleeping, shaking, fits, irregular heartbeat, palpitations, stomach pain, sweating, facial flushing, general discomfort, loss of appetite, very slow or shallow breathing, shortness of breath, hallucinations, nightmares, cramps or stiffness.
- 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 to 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.

5. How to store Syndol

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use after the expiry date (EXP) which is stated on the carton and blister. The expiry date refers to the last day of that month.
- If you have any tablets left over, you may return them to your pharmacy for safe disposal.
- If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

6. Contents of the pack and other information

Each Syndol tablet contains 450mg paracetamol, 10mg codeine phosphate hemihydrate, 5mg doxylamine succinate and 30mg caffeine as the active ingredients.

The other ingredients are: corn starch, povidone, talc, magnesium stearate, croscarmellose sodium, hypromellose, polyethylene glycol 400, quinoline yellow aluminium lake (E104), sunset yellow aluminium lake (E110), titanium dioxide (E171), lactose and polyethylene glycol 4000.

Syndol are yellow, capsule shaped tablets, embossed 'SYNDOL' on one side with a single breakline on the reverse.

Syndol are supplied in blister packs of 20.

Manufacturer

Manufactured by: Simco Ltd, Braye Road Industrial Estate, Vale, Guernsey, Channel Islands, UK or SSL International plc, Whitehouse Industrial Park, Traynor Way, Peterlee, Durham, SR8 2RU, UK.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/111/1

Leaflet issue and revision date (ref): 29.01.13

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