

Package leaflet: Information for the user

Tylex® 30 mg / 500 mg capsules, hard
Codeine phosphate hemihydrate, Paracetamol

This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.
- In this leaflet, Tylex 30 mg / 500 mg Capsules, hard will be called Tylex.

What is in this leaflet

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

1. What Tylex is and what it is used for

This medicine has been prescribed for you for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone, in adults and children over 12 years of age. It contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. It also contains paracetamol, another analgesic, to relieve pain.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Tylex

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

Do not take Tylex:

- if you are allergic to paracetamol or codeine phosphate hemihydrate or any of the other ingredients of this medicine (listed in section 6).
- 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.
- if you are a child under 12 years of age.
- if you know that you metabolise codeine into morphine very rapidly.
- if you have severe asthma attacks or severe breathing problems.

- if you are an alcoholic.
- if you have recently had an operation on your liver, gallbladder or bile duct (biliary tract).
- if you have recently had a head injury.
- if 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.
- if you are breastfeeding.
- if you are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypromine (see 'Taking other medicines').

Warnings and precautions

Talk to your doctor or pharmacist before taking Tylex if:

- you have liver or kidney disease
- you have an underactive thyroid gland
- you suffer from urinary problems (e.g. difficulty in passing water), including those associated with an enlarged prostate gland
- you have a condition affecting your pancreas and bile ducts (diseases of the biliary tract)
- you have a disease of the adrenal gland called Addison's disease
- you have decreased brain functioning
- you have inflammatory or obstructive bowel disorders (such as colitis or Crohn's disease or a blockage of your bowel)
- you have a condition called myasthenia gravis which weakens the muscles
- you are elderly
- you feel weak
- you are debilitated
- you are sensitive to aspirin or other medicines used for the treatment of inflammation (non steroidal anti-inflammatory drugs) such as ibuprofen
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- you feel you need to take more of Tylex to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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.

Children and adolescents

Tylex should be used with extreme caution in adolescents between 12 and 18 years. An alternative medicine should be considered if at all possible.

Use in adolescents between 12 and 18 years with breathing problems

Codeine is not recommended in adolescents between 12 and 18 years with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and Tylex

Do not take Tylex with any other paracetamol-containing products. Many other medicines contain paracetamol, including some you can buy without a prescription (for example some cold and “flu” remedies).

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 taken them in the last 2 weeks.
MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine, selegiline.

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

- Medicines to treat anxiety or depression (e.g. fluoxetine, paroxetine, amitriptyline, doxepin, nortriptyline)
- Other painkillers (including opioids)
- Medicines to help you sleep
- Warfarin (a medicine used to thin the blood)
- Medicines used to treat stomach problems, sickness or feeling sick (including metoclopramide and domperidone)
- Cholestyramine (a medicine used to lower cholesterol levels in the blood)
- Medicines to help relax muscles
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see section 2).
- Rifampicin - an antibiotic used for infections
- Phenytoin, phenobarbital, carbamazepine (medicines to treat epilepsy)
- Bupropion (a medicine used to treat depression and smoking cessation)
- Any other medicine, including medicines obtained without a prescription (e.g. St. John's wort).

Concomitant use of Tylex and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Tylex together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Concomitant use of Tylex with certain antidepressants and antipsychotics may result in a small risk of so-called serotonin syndrome. The symptoms of this syndrome can include mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38 °C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Seek medical advice immediately if you have any of the above symptoms related to this serious syndrome.

Tylex with food, drink and alcohol

Do not drink alcohol whilst taking Tylex. If you regularly drink large amounts of alcohol, you are at risk of damaging your liver when taking paracetamol.

Pregnancy, breast-feeding and fertility

Do not take Tylex if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Tylex during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Tylex while you are breastfeeding as codeine passes into breast milk and will affect your baby.

Driving and using machines

The medicine can affect your ability to drive, operate machinery and carrying out complex tasks 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.

Tylex contains sodium metabisulfite and sodium benzoate

Tylex contains **sodium metabisulfite** and is unsuitable for people who are sensitive to sulfite. People with **asthma** are more likely to be sensitive to sulfite. Therefore, you should talk to your doctor before taking Tylex if you are sensitive to sulfite or if you suffer from **asthma**. May rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

This medicine contains 0.3 mg sodium benzoate salt in each capsule, which is equivalent to 0.3 mg / 547.86 mg capsule.

3. How to take Tylex

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your prescriber should have discussed with you, how long the course of capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults and the elderly

- Swallow the Tylex capsule with water
- The label will tell you how many capsules to take and how often
- The recommended dose is one or two capsules every 4 hours
- Do not take more than eight capsules in 24 hours
- Leave at least 4 hours between doses
- If you are elderly you may need to take fewer capsules. Please speak to your doctor about this.
- If you feel the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that the pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist. Do not take more than 8 capsules in 24 hours.

Use in children and adolescents

Children aged less than 12 years:

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

Children aged 12 to 15 years:

One capsule every 6 hours when necessary (do not take more than four capsules in 24 hours).

Children aged 16 to 18 years:

One to two capsules every 6 hours when necessary (do not take more than eight capsules in 24 hours).

Duration of treatment

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

If you take more Tylex than you should

Do not take more Tylex than you should. If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor. You should go to hospital, even if you feel well, because there is a risk of delayed, serious liver damage.

If you forget to take Tylex

It is important that you take Tylex at the right times. If you forget to take a dose, take it as soon as you remember, then carry on as before.

Do not take more than two capsules at once.

If you stop taking Tylex

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek immediate medical help if you have any of the following symptoms:

- **Feeling faint**
- **Swelling of the hands, feet, ankles, face, lips or throat or blistering of the skin, mouth, eyes and genitals. You could also notice an itchy, lumpy rash (hives) or nettle rash. This may mean you are having an allergic reaction to this medicine.**
- **Difficulty in breathing or wheezing, shortness of breath.**
- **You get serious skin reactions. Very rare cases have been reported**

See your doctor as soon as possible if you have problems with the blood (thrombocytopenia, agranulocytosis, neutropenia, leucopenia). This is usually shown by tiredness, weakness, or unexplained bruising or bleeding. This side effect is very rare.

Frequency “Not known” (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Tell your doctor or pharmacist if you notice any of the following side effects get serious or last longer than a few days:

- Allergic reactions, including skin rash
- Feeling sick or being sick
- Light-headedness
- Confusion
- Dizziness
- Feeling sleepy
- Headache
- Mood changes
- Hallucination
- Difficulty in breathing, shortness of breath, wheezing, tightness in the chest (bronchospasm)
- Constipation
- Severe stomach pains (pancreatitis)
- Sharp pain after eating in upper part of the abdomen (biliary spasm)
- Stomach pains
- Itchy skin
- Deafness
- Difficulty in passing water (urine)
- Unknown frequency: dependence and addiction (see section “How do I know if I am addicted?”)

Taking codeine regularly for a long time can lead to addiction.

Drug Withdrawal

When you stop taking Tylex, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted

If you notice any of the following signs whilst taking Tylex, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Taking Tylex for headaches too often or for too long can make the headaches worse.

Taking a lot of Tylex for a long time can cause deafness.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Tylex

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

Do not use this medicine after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Store at or below 25°C. Keep container in the outer carton.

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 Tylex contains

- The active substances are codeine phosphate hemihydrate and paracetamol. Each capsule contains 30mg codeine phosphate hemihydrate and 500mg paracetamol.
- The other ingredients are sodium metabisulfite (E223), pregelatinised starch, calcium stearate, docusate sodium with sodium benzoate (E211). The capsule is made of gelatin, titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132). The printing ink contains shellac, propylene glycol, ammonium hydroxide and iron oxide black (E172).

What Tylex looks like and contents of the pack

Tylex capsules are hard gelatin capsules with white opaque body and red cap, both with C30 printed on them in black.

They are supplied in blister strips containing 7, 8, 14, 24, 28, 100, 300 or 600 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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