

## Package leaflet: Information for the user

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

Can cause addiction Contains opioid
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### **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**

Tylex is used in adults and 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.

This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

### **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.

#### **Important information about Tylex:**

- Do not take for longer than directed by your prescriber
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the capsules
- Taking a painkiller for headaches too often or for too long can make them worse.

#### **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 very rapidly codeine into morphine.
- 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**

### **Children and adolescents**

Tylox 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 children and adolescents after surgery

Codeine should not be used 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.

#### 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.

### **Talk to your doctor or pharmacist before taking Tylox 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.

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.

### **Other medicines and Tylox**

**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
- 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.

### **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 trying to become pregnant without first talking to your doctor or pharmacist.

Do not take Tylex and speak to your doctor or pharmacist if:

- You are in the last three months of pregnancy
- In labour

Do not take Tylex while you are breastfeeding. Codeine and morphine passes into breast milk.

### **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.

### **Tylox contains sodium metabisulfite**

Tylox 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 Tylox if you are sensitive to sulfite or if you suffer from **asthma**.

### **3. How to take Tylox**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **Adults and the elderly**

- Swallow the Tylox 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:*

Tylox 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 Tylox than you should**

Do not take more Tylox 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**

You may feel irritable or restless when treatment with Tylex is stopped.

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.

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)
- Becoming dependent on codeine

Taking codeine regularly for a long time can lead to addiction. This might cause you to feel restless and irritable when you stop taking Tylex.

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](http://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**

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire SL1 3WE, UK.

### **Manufacturer**

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A, Estrada Consiglieri Pedroso, no. 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal.

### **This leaflet was last revised in March 2020.**

If this leaflet is difficult to read and you would like it in a different format, please contact UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.