

Package leaflet: Information for the patient

Tylex[®] 30 mg/500 mg Tablets

Codeine Phosphate Hemihydrate 30 mg, Paracetamol 500 mg

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 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 symptoms 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 Tablets 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 can be 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 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..

2. What you need to know before you take Tylex

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 tablets
- Taking a painkiller for headaches too often or for too long can make them worse.

Do not take Tylex:

- 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 know that you metabolise very rapidly codeine into morphine
- If you are breastfeeding
- You are allergic to paracetamol or codeine phosphate hemihydrate, or any of the other ingredients of this medicine (listed in section 6)
- You are taking other paracetamol containing medicines
- You are pregnant without first talking to your doctor
- You are a child under 12 years old

If any of the above applies to you talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tylex.

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

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.

Check with your doctor before taking Tylex if:

- You have asthma (see end of section 2) or any conditions that affect your breathing
- You have had a serious head injury or raised pressure on the brain
- 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 disease of the adrenal gland called Addison's disease
- You have decreased brain functioning
- You have inflammatory or obstructive bowel disorders
- You have a condition called myasthenia gravis which weakens the muscles
- You are elderly
- You feel weak
- You are debilitated

If any of the above applies to you, talk to your doctor before taking Tylex.

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).**
- **Tell your doctor if you are taking any of the following medicines:**
 - Medicines to treat anxiety or depression
 - Other painkillers
 - Medicines to help you sleep

- Warfarin (a medicine used to thin the blood)
- Medicines used to treat stomach problems, sickness or feeling sick
- Products used to treat diarrhoea (including metaclopramide and domperidone)
- Cholestyramine (a medicine used to lower cholesterol levels in the blood)
- Medicines to help relax muscles
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you, talk to your doctor before taking Tylex.

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

Driving and using machines

Tylex may make you feel dizzy or tired. If this happens to you, do not drive a vehicle, operate machinery or carry out complex tasks.

3. How to take Tylex

Always take Tylex exactly as your doctor has told you.

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.

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.

Adults and the elderly

- Swallow the Tylex tablet with water
- The label will tell you how many tablets to take and how often
- The usual dose is one or two tablets every 6 hours
- Do not take more than eight tablets in 24 hours
- If you are elderly you may need to take fewer tablets. Please speak to your doctor about this.

Use in children and adolescents

Children aged 12 years or above should take Tylex tablets every 6 hours, as needed. Do not take more than eight tablets in 24 hours. Tylex should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

If you feel the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

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 tablets 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, Tylex 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**
- **Difficulty in breathing or wheezing, shortness of breath**

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
- Dizziness
- Feeling sleepy
- Mood changes
- Constipation
- Severe stomach pains (pancreatitis)
- Stomach pains
- Itchy skin
- Deafness
- Problems with the blood (thrombocytopenia and agranulocytosis). This is usually shown by tiredness, weakness, or unexplained bruising or bleeding. This side effect is very rare.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

UK

The Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

5. How to store Tylex

Keep out of the sight and reach of children.

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

Store below 25°C. Store in the original packaging and in a dry place to protect it from light and moisture.

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 this pack and other information

What Tylex contains

There are two active substances in Tylex: codeine phosphate hemihydrate (30 mg) and paracetamol (500 mg).

The other ingredients are; powdered cellulose, sodium starch glycolate, maize starch, pregelatinized starch, magnesium stearate, colloidal silica anhydrous, carnauba wax, purified water and Opadry® 11 white film coating (contains lactose, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol).

The printing ink contains: Shellac, ethylalcohol, isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide, conchineal (EEC No. 120).

What Tylex looks like and contents of the pack

Tylex tablets are white, film-coated, capsule-shaped tablets with "TYLEX" printed on both sides.

They come in bottles containing 8, 24, 32, 40, 48, 56, 64, 100, or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

UCB Pharma Ltd, 208 Bath Rd, Slough, Berkshire, SL1 3WE, UK.

This leaflet was last revised in June 2014.

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