Tylex®
30 mg / 500 mg
hard capsules
Codeine Phosphate Hemihydrate 30 mg
Paracetamol 500 mg

Read all of this leaflet carefully before you start taking this medicine.
• Keep this leaflet. You may need to read it again
• If you have further questions, please ask your doctor or pharmacist
• This medicine has been prescribed for you. Do not pass it on to others, it may harm them, even if their symptoms are the same as yours
• In this leaflet Tylex 30 mg / 500 mg Hard Capsules will be called Tylex.

In this leaflet:
1. What Tylex is for
2. Before you take Tylex
3. How to take Tylex
4. Possible side effects
5. How to store Tylex
6. Further information.

1. What Tylex is for

Tylex is a painkiller (analgesic) taken to relieve moderate pain.
Tylex can be used 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. Before you take Tylex

Do not take Tylex if:
• You are allergic to paracetamol or codeine phosphate hemihydrate, or to any of the other ingredients in Tylex (see section 6)
• You are taking other Paracetamol containing medicines
• You are a child under 12 years old.
• 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

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

Warnings and precautions
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 section 2) or any conditions affecting your breathing
• You had a serious head injury or raised pressure on the brain
• You have sudden and short-lasting stomach conditions
• You have liver or kidney disease
• You have an under-active 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 gallbladder or bile duct disorders (biliary tract disorders)
• You have recently had surgery on your gallbladder or bile ducts (biliary tract)
• You have a condition which weakens the muscles called myasthenia gravis
• You suffer from neuromuscular disorders (lack of control of muscle movment).
• You have heart or chest conditions.
• You have a condition called ulcerative colitis which affects your colon
• You have a condition that causes your body to have less blood than it should
• You have fits (seizures)
• You are suffering from shock
• You have been told by a doctor that your body uses codeine too quickly (ultra-rapid metaboliser)
• You are elderly
• You feel weak.
If any of the above applies to you, talk to your doctor before taking Tylex.

Taking other medicines
• 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)
• Quinidine (a medicine used to treat heart rhythm disorders)
• 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.

Taking Tylex with food and drink
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 and breast-feeding
Do not take Tylex if you are pregnant,trying to get pregnant or breastfeeding your baby without first talking to your doctor.
Usually it is safe to take Tylex while breast feeding as the level of the active ingredients of this medicine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels in their breast milk. If any of the following side effects develop in you or your baby stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

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.

Warnings about the ingredients in Tylex
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.**

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.

Adults and the elderly
• Swallow the Tylex capsule with water
• The label will tell you how many capsules to take and how often
• The usual dose is one or two capsules every 6 hours
• Do not take more than eight capsules in 24 hours

• If you are elderly you may need to take fewer capsules. Please speak to your doctor about this.

Children aged 12 years of above should take Tylex every 6 hours, as needed. Do not take more than 8 capsules in 24 hours. 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.
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 your capsules 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 and do not take more than eight capsules in each 24-hour period.**

If you stop taking Tylex
You may feel irritable or restless when treatment with Tylex is stopped.

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
• Shortness of breath
• Feeling sick or being sick
• Light-headedness
• Dizziness
• Feeling sleepy

• Mood changes
• Constipation
• Severe stomach pains (pancreatitis)
• Stomach pains
• Itchy skin
• 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 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tylex
Keep out of the reach and sight of children.
Do not use Tylex after the expiry date on the carton and each blister strip.
The expiry date refers to the last day of that month. On the packaging, the term “expiry date” has been shortened to “EXP”.
Store below 25°C. Store in the original packaging and in a dry place to protect it from light and moisture.
Medicines should not be disposed of via wastewater or household waste.
Return all unused medicine to your pharmacist.

6. Further information

What Tylex contains
There are two active substances in Tylex: codeine phosphate hemihydrate (30 mg) and paracetamol (500 mg).
The other ingredients are: The other ingredients are; sodium metabisulfite (E223), pregelatinised potato starch, calcium sodium benzoate (E211)). The capsule is made of gelatin, titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132). The printing ink contains shellac, soya lecithin, 2-ethoxyethanol, dimeticone and iron oxide (E172).

What Tylex looks like
Tylex capsules are red and white with C30nprinted on them. They come in bottles containing 8, 100, or 500 capsules. They also are supplied in blister strips containing 8, 24 or 100 capsules.. Not all pack sizes may be marketed.

Marketing Authorisation Holder
UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive,
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Manufacturer
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This leaflet was last updated 05/2015
If this leaflet is difficult to read and you would like it in a different format, please contact UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.