

Package leaflet: Information for the user
Tylex® 30 mg / 500 mg Effervescent Tablets

Codeine phosphate hemihydrate,
Paracetamol

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.

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 contains two different medicines called paracetamol and codeine phosphate hemihydrate. 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. Paracetamol is an analgesic which acts to relieve pain.

Tylex is used in adults and adolescents from 12 to 18 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

2. What you need to know before you take Tylex

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).
- if 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 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

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 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 Tylex:

- if you have liver or kidney disease
- if you have an under-active thyroid gland
- if you suffer from urinary problems (e.g. difficulty in passing water) including those associated with an enlarged prostate gland
- if you have a disease of the Adrenal gland called Addison's disease
- if you have a condition which weakens the muscles called myasthenia gravis
- if you have been told to restrict your sodium intake
- if you have a metabolic disorder called phenylketonuria, which requires a diet low in an amino acid called phenylalanine
- if you have a condition called ulcerative colitis which affects your colon
- if you have a condition that causes your body to have less blood than it should
- if you have fits (seizures)
- if you are suffering from shock
- if you are elderly
- if you feel weak.

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

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

- Chloramphenicol - an antibiotic used for infections
- The oral contraceptive pill
- Medicines to treat anxiety or depression (e.g. fluoxetine, paroxetine or sertraline)

- 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 metaclopramide and domperidone)
- Cholestyramine (a medicine used to lower cholesterol levels in the blood)
- Rifampicin - an antibiotic used for infections
- Phenytoin, phenobarbital, carbamazepine (medicines to treat epilepsy)
- Quinidine (a medicine used to treat heart rhythm disorders)
- Medicines to help relax muscles
- Neuroleptics (a medicine use to treat schizophrenia and bipolar disorder)
- Bupropion (a medicine use 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 get 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

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.

Tylex contains aspartame and sodium

This medicine contains 25 mg aspartame in each tablet which is equivalent to 25 mg/ 2880 mg tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 326.6 mg sodium (main component of cooking/table salt) in each. This is equivalent to 16 % of the recommended maximum daily dietary intake of sodium for an adult. May not be suitable for people on a controlled sodium diet.

Tell your doctor or pharmacist before taking this medicine if either of the above statements applies to you.

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.

Adults and the elderly

- The recommended dose is one or two tablets every 6 hours
- Do not take more than eight tablets in 24 hours
- Dissolve the tablet in one glass of water
- Drink the whole contents of the glass
- The label will tell you how many tablets to take and how often
- 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 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 tablet every 6 hours when necessary (do not take more than four tablets in 24 hours).

Children aged 16 to 18 years:

One to two tablets every 6 hours when necessary (do not take more than eight tablets 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 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 tablets 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 and do not take more than eight tablets in each 24-hour period.**

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**

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)
- Stomach pains
- Itchy skin
- Deafness
- Difficulty in passing water (urine)
- Becoming dependent on codeine
- 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.

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 HPRAs Pharmacovigilance, Website: www.hpra.ie.

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 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. Further information

What Tylex contains

- The active substances are codeine phosphate hemihydrate and paracetamol. Each tablet contains 30mg codeine phosphate hemihydrate and 500mg paracetamol.
- The other ingredients are anhydrous citric acid, sodium hydrogen carbonate, anhydrous sodium carbonate, aspartame (E951), macrogol 6000 and magnesium stearate.

What Tylex looks like and contents of the pack

Tylex effervescent tablets are round and white or off-white.

They come in packs of 6, 8, 24, 30, 36, 42, 48, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer

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

This leaflet was last revised in upon approval.

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.