

ULTRAMOL SOLUBLE

Paracetamol, Codeine phosphate and Caffeine

Is this leaflet hard to see or read?

Phone 01483 505515 for help

SANOFI **Important things you should know about Ultramol Soluble**

- **This medicine can only be used for the short term treatment of acute moderate pain when other painkillers have not worked**
- **You should only take this product for a maximum of 3 days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice**
- **This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it**
- **If you take this medicine for headaches for more than 3 days it can make them worse**

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 questions, ask your doctor or pharmacist. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. WHAT ULTRAMOL SOLUBLE IS AND WHAT IT IS USED FOR

The name of your medicine is Ultramol Soluble. Ultramol Soluble contains three different medicines called paracetamol, codeine phosphate and caffeine. 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 painkillers such as paracetamol. Ultramol Soluble is for the short term treatment of acute moderate pain caused by headaches, migraine, toothache, neuralgia, period pain and rheumatic pains when other painkillers have not worked. Wait at least 4 hours after you last took other painkillers before taking this medicine. Ultramol can be used in 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ULTRAMOL SOLUBLE

- **This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it**
- **If you take a painkiller for headaches for more than 3 days it can make them worse**

Warnings and precautions

Do not take Ultramol Soluble and tell your doctor if:

- You are allergic (hypersensitive) to the active substances or any of the other ingredients in your medicine (listed in Section 6). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.
- The person going to take the tablets is under 12 years of age. Ultramol Soluble must not be given to children under 12 years of age.
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome
- You know that you metabolise very rapidly codeine into morphine
- You are breastfeeding or planning to breastfeed

Talk to your doctor straight away if you notice any of the following serious side effects:

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- | | |
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| • Constipation | • Stomach pain, indigestion, nausea or vomiting. These can be signs that the caffeine is irritating your stomach. |
| • Feeling sick (nausea), being sick (vomiting) | • Headaches |
| • Dizziness, light-headedness, drowsiness, confusion | • Tremor |
| • Difficulty in passing water | • Nervousness |
| • You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia) | • Irritability |
| | • Sleeplessness |
| | • Palpitations |
| | • Becoming addicted to codeine |

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. By reporting side effects, you can help provide more information on the safety of this medicine.

How do I know if I am addicted?

If you take this medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- **You need to take the medicine for longer periods of time**
- **You need to take more than the recommended dose**
- **When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again**

5. HOW TO STORE ULTRAMOL SOLUBLE

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

Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Store your medicine in the original packaging in order to protect from moisture.

Do not store above 30°C.

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 Ultramol Soluble Tablets contain**

- The active substances are paracetamol, codeine phosphate and caffeine. Each tablet contains 500mg of paracetamol, 8mg of codeine and 30mg of caffeine.
- The other ingredients are sodium bicarbonate, citric acid, sodium carbonate, sorbitol, saccharin sodium, povidone, dimethicone, and sodium lauryl sulphate.

What Ultramol Soluble tablets look like and contents of pack

Flat white tablets with bevelled edges, plain on one side and scored on the other. Each pack contains 32 tablets.

The Marketing Authorisation Holder is Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

The Manufacturer is Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT, UK

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Do not take Ultramol Soluble if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Ultramol Soluble.

Take special care and check with your doctor before taking Ultramol Soluble if:

- You have severe kidney or liver problems
- You have non-cirrhotic alcoholic liver disease

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

Ultramol 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

Ultramol is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Ultramol Soluble

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Ultramol Soluble can affect the way some other medicines work. Also, some other medicines can affect the way Ultramol Soluble works.

While taking Ultramol Soluble you should not take any other medicines which contain paracetamol. This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine and tell your doctor or pharmacist if you are taking the following:

- Medicines used to thin the blood such as warfarin
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Ultramol Soluble.

Ultramol Soluble with drink

Drinking too much coffee, or other drinks containing caffeine, while taking these tablets, may make you tense and irritable.

Pregnancy and breast-feeding

Talk to your doctor before taking these tablets if:

- You are pregnant, think you may be pregnant or plan to get pregnant
- You are planning to breastfeed
- Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

Co-codamol can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive whilst 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 whilst taking this medicine.

Ultramol Soluble contains sodium and sorbitol

- **Sodium:** There is 362mg of sodium per effervescent tablet. This may be harmful to people on a low sodium or low salt diet.
- **Sorbitol:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE ULTRAMOL SOLUBLE

Always take Ultramol Soluble exactly as instructed on this leaflet. Check with your doctor or pharmacist if you are not sure.

- **Do not take more than the recommended dose**
- **Do not take for more than 3 days. If the pain does not improve after 3 days you must speak to your doctor or pharmacist for advice**

Adults and children over 12

- The usual dose of Ultramol Soluble is 2 effervescent tablets, taken together
- Dissolve the effervescent tablets in a full glass of water before taking
- Adults should wait at least 4 hours before taking another dose
- Children aged 12 years and over should wait at least 6 hours before taking another dose
- Do not take more than 8 tablets in any 24-hour period

Use in children

Ultramol Soluble should not be given to children under 12 years of age due to the risk of severe breathing problems.

If you take more Ultramol Soluble than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken

If you forget to take Ultramol Soluble

If you forget to take a dose at the right time, take it as soon as you remember. However do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

If you stop taking Ultramol

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. POSSIBLE SIDE EFFECTS

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

Important side-effects you should know about Ultramol Soluble

- Taking a painkiller for headaches too often or for too long can make them worse.
- Taking Ultramol Soluble regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.

Stop taking Ultramol Soluble and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria) This may mean you are having an **allergic reaction** to Ultramol Soluble
- You get serious skin reactions. Very rare cases have been reported.