

## PACKAGE LEAFLET – INFORMATION FOR THE USER

### ULTRAMOL SOLUBLE

Paracetamol, Codeine phosphate and Caffeine

#### **⚠ 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. See section 4.

#### **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 or pharmacist 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.

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 or pharmacist before taking Ultramol Soluble if:**

- You have severe kidney or liver problems
- You have non-cirrhotic alcoholic liver disease
- You have suffered from alcoholism, drug abuse, or dependence
- You have problems passing water or prostate problems.
- You have a bowel problem such as colitis or Crohn's

disease or a blockage of your bowel.

- You are elderly.
- You have a condition called myasthenia gravis which weakens the muscles.
- You suffer from hypothyroidism.
- You have a disease of the adrenal gland called Addison's disease
- You are taking a benzodiazepine (used for the treatment of anxiety or sleep disorders), e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam.

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.

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are**

#### **taking or have taken within the last two weeks:**

- monoamine oxidase inhibitors (MAOIs) such as moclobemide and phenelzine used in the treatment of depression
  - medicines which make you drowsy or sleepy (CNS depressants and benzodiazepines) such as medicines used to treat anxiety or anaesthetics.
  - medicines for depression such as dosulepin, mirtazapine (tricyclic) or chlorpromazine (phenothiazines)
  - medicines known as tranquillisers, or hypnotics
  - sleeping tablets, sedatives and some antihistamines
- You may experience more drowsiness if you take these medicines with Ultramol Soluble.

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Because of this, you should only take these together if prescribed by your doctor. Please follow your doctor's dosage 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.

#### **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.

#### **Please inform your doctor or pharmacist if you are taking:**

- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

#### **Tell your doctor or pharmacist if you are taking:**

- 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 and alcohol**

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

Ask your doctor or pharmacist before taking codeine if you have:

- suffered from alcoholism, drug abuse, or dependence.

#### **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**

Ultramol Soluble 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:** This medicine contains 388 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 19.4 % of the recommended maximum daily dietary intake of sodium for an adult.

**Sorbitol:** This medicine contains 50 mg sorbitol in each effervescent tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive 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**
- **Dissolve the effervescent tablets in a glass of water before taking.**

**Adults:** 2 tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

**Children aged 16 to 18 years:** 1 to 2 tablets every 6 hours when necessary up to a maximum of four doses in 24 hours.

**Children aged 12 to 15 years:** 1 tablet every 6 hours when necessary to a maximum of four doses in 24 hours.

**Children aged under 12 years:** 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 Soluble**

**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.

#### **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:**

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

#### **⚠ 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**

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

#### **The Manufacturer is**

LAMP SAN PROSPERO SPA, VIA DELLA PACE 25/A, SAN PROSPERO (MO) 41030, Italy

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