

**RENLAUCOL 500 mg / 30 mg**  
**Effervescent tablets**  
Paracetamol and Codeine Phosphate Hemihydrate

**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. 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 RENLAUCOL 500 mg / 30 mg, effervescent tablets are and what they are used for
2. Before you take RENLAUCOL 500 mg / 30 mg, effervescent tablets
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**1. What RENLAUCOL 500 mg / 30 mg, effervescent tablets are and what they are used for**

RENLAUCOL 500 mg / 30 mg, effervescent tablets contain paracetamol and codeine. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. RENLAUCOL 500 mg / 30 mg, effervescent tablets can be used in children and adolescents aged 12 years and older and in adults for the short-term treatment of moderate to severe pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

**2. What you need to know before you take RENLAUCOL 500 mg / 30 mg, effervescent tablets**

**Do not take RENLAUCOL 500 mg / 30 mg, effervescent tablets if:**

- you are allergic to paracetamol or codeine, or any of the other ingredients of this medicine (listed in section 6)
- you suffer from breathing problems, for example chronic bronchitis or emphysema or are suffering an asthma attack
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs, such as phenelzine, moclobemide or isocarboxazid are medicines used to treat depression
- you have just had a head injury or suffer from increased pressure on the brain
- you have severe problems with your kidneys or liver
- you drink a lot of alcohol
- you have recently had an operation to your gall bladder
- in children and adolescents (0-18 years of age) for pain relief after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- you know that you metabolise very rapidly codeine into morphine

- you are breastfeeding

RENLAUCOL 500 mg / 30 mg, effervescent tablets should not be taken by children under 18 years of age.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking RENLAUCOL 500 mg / 30 mg, effervescent tablets if:

- you have any stomach pains or other sudden problems in your abdomen (belly)
- you are prone to suffer from asthma
- you are elderly
- you have liver or kidney problems, because the dose might need to be lower
- your prostate is larger than normal or you have a narrowing of your urethra (tube through which urine is passed)
- you feel you have taken RENLAUCOL 500 mg / 30 mg, effervescent tablets for a long time. You may develop a dependence on RENLAUCOL 500 mg / 30 mg, effervescent tablets which may be harmful.

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.

### Long-term treatment

Taking codeine (an active ingredient of RENLAUCOL 500 mg / 30 mg, effervescent tablets) regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.

### **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.

### **Other medicines and RENLAUCOL 500 mg / 30 mg, effervescent tablets**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- Medicines to treat depression such as amitriptyline, fluoxetine, sertraline etc.
- Medicines used to treat high blood pressure such as furosemide, amiloride or bendroflumethazide

- MAOIs used to treat depression, taken within the last 14 days (refer to “do not take if” in section 2 above)
- Medicines to treat mental illness, e.g. chlorpromazine, haloperidol etc.
- Sedatives and sleeping tablets, e.g. temazepam and diazepam
- Medicines for irregular heartbeats (mexiletine, quinine or quinidine)
- Drugs used to dry fluids in the mouth and lungs known as anticholinergics
- Medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- Medicines to treat epilepsy (e.g. phenytoin and carbamazepine)
- Rifampicin (an antibiotic)
- St John’s Wort (*Hypericum perforatum*)
- Colestyramine, used to treat high levels of lipids in your blood, or for problems related to your bile duct.
- Ritonavir, used to treat HIV
- Other strong painkillers called opioids
- Medicines which prevent blood clotting (anticoagulants such as warfarin).

RENLAUCOL 500 mg / 30 mg, effervescent tablets must not be taken with any other medicines containing paracetamol or codeine. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

### **RENLAUCOL 500 mg / 30 mg, effervescent tablets with food and drink**

Do not drink alcohol whilst taking RENLAUCOL 500 mg / 30 mg, effervescent tablets.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant, think you may be pregnant or are planning to become pregnant speak to your doctor or pharmacist before taking this medicine.

#### *Pregnancy*

RENLAUCOL 500 mg / 30 mg, effervescent tablets should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born.

#### *Breast-feeding*

Do not take RENLAUCOL 500 mg / 30 mg, effervescent tablets while you are breast feeding. Codeine, morphine and paracetamol pass into breast milk.

#### *Fertility*

There is no information concerning the effect of RENLAUCOL 500 mg / 30 mg, effervescent tablets on fertility.

### **Driving and using machines**

RENLAUCOL 500 mg / 30 mg, effervescent tablets may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.

### **RENLAUCOL 500 mg / 30 mg, effervescent tablets contains sorbitol and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicinal product contains 17.9 mmol (413 mg) sodium per tablet. To be taken into consideration by patients on a controlled sodium (salt) diet.

### **3. How to take RENLAUCOL 500 mg / 30 mg, effervescent tablets**

Always take RENLAUCOL 500 mg / 30 mg, effervescent tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Dosage:**

The usual dose is one or two tablets every four hours as needed. You should not take more than 8 tablets in 24 hours. If you feel the effect of RENLAUCOL 500 mg / 30 mg, effervescent tablets is too strong or too weak, talk to your doctor or pharmacist.

*Elderly*

A lower dosage may be needed if you are elderly or have other medical problems. Check with your doctor about this.

*Use in children*

RENLAUCOL 500 mg / 30 mg, effervescent tablets should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Children aged 12 to 18 years should take RENLAUCOL 500 mg / 30 mg, effervescent tablets every 6 hours, as needed, according to the doctor's instructions. You should not take more than 8 tablets in 24 hours. The maximum daily dose of codeine should not exceed 240 mg.

**Method of administration**

The tablets must be put in a glass of water and allowed to completely dissolve. Drink the resulting solution immediately. Do not chew or bite your tablets.

**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. Do not take this medicine longer than as directed by your doctor.

**If you take more RENLAUCOL 500 mg / 30 mg, effervescent tablets than you should**

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Bring the remaining tablets and this leaflet with you so that the medical staff know what you have taken.

**If you forget to take RENLAUCOL 500 mg / 30 mg, effervescent tablets**

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

**If you stop taking RENLAUCOL 500 mg / 30 mg, effervescent tablets**

RENLAUCOL 500 mg / 30 mg, effervescent tablets can become habit forming. This is called dependence (addiction). If you stop taking your medicine suddenly it can cause withdrawal symptoms such as restlessness and irritability. Your doctor will stop your tablets gradually to avoid you having these withdrawal symptoms. If you find you need to use this product all the time, it is important to consult your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

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

**All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.**

**The following side effects are serious. Talk to you doctor straight away if you notice them:**

Very common (may affect more than 1 in 10 people)

- shortness of breath
- feeling overly elated or depressed

Rare (may affect up to 1 in 1,000 people):

- Unusual bruising, or infections such as sore throats - this may be a sign of very rare changes in the blood
- Not known (frequency cannot be estimated from the available data) confusion
- small eye pupils, problems with vision
- slow or weak breathing
- yellowing of the skin or whites of the eyes (symptoms of liver damage)
- difficulty in passing urine

**Other side effects include:**

Very common (may affect more than 1 in 10 people):

- light headedness, dizziness, sleepiness, headache\*
- feeling sick (nausea), being sick (vomiting)
- constipation, stomach pain
- skin rashes or itching

\*If a pain killer is used too long for the treatment of headaches, it can make them worse.

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

## **5. How to store RENLAUCOL 500 mg / 30 mg, effervescent tablets**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister or bottle after “EXP”. The expiry date refers to the last day of that month.

*For the polypropylene tubes:*

Store in the original polypropylene tubes.

Keep the tubes tightly closed in order to protect from moisture.

*For the foil strips:*

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What RENLAUCOL 500 mg / 30 mg, effervescent tablets contain**

- The active substances are Paracetamol, 500 mg and Codeine Phosphate Hemihydrate, 30 mg.
- The other ingredients are sodium hydrogen carbonate, sodium carbonate anhydrous, citric acid anhydrous, sodium docusate, sorbitol, saccharin sodium, dimeticone, sodium benzoate, macrogol 6000 and natural grapefruit flavour.

### **What RENLAUCOL 500 mg / 30 mg, effervescent tablets looks like and contents of the pack**

RENLAUCOL 500 mg / 30 mg, effervescent tablets are white circular tablets with a score line on one face. Although your tablets are scored they must not be halved as they will not give an equal dose.

RENLAUCOL 500 mg / 30 mg, effervescent tablets are available in:

- aluminium/polyethylene foils strips of 4, 8, 16, 32 and 100 effervescent tablets
- polypropylene tubes of 8, 16, 32 and 96 effervescent tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

MG Pharma  
24 Rue Erlanger  
75016 Paris  
France

### **Manufacturer**

Unither Industries  
ZI le Malcourlet  
03800 Gannat  
France

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Ireland: Renlaucol  
Sweden: Renlaucol

**This leaflet was last revised in {07/2014}.**

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