

## Package Leaflet: Information for the user

### Maxilief Effervescent Tablets

Paracetamol	500mg
Codeine Phosphate Hemihydrate	8mg
Caffeine	30mg

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### What is in this leaflet

1. What Maxilief Effervescent Tablets are and what they are used for
2. What you need to know before you take Maxilief Effervescent Tablets
3. How to take Maxilief Effervescent Tablets
4. Possible side effects
5. How to store Maxilief Effervescent Tablets
6. Contents of the pack and other information.

### **1. WHAT MAXILIEF EFFERVESCENT TABLETS ARE AND WHAT THEY ARE USED FOR**

Maxilief Effervescent Tablets contain paracetamol 500 mg, codeine phosphate hemihydrate 8 mg and caffeine 30 mg.

Paracetamol is an analgesic (a painkiller) and an antipyretic (reduces fever). 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. Codeine phosphate hemihydrate also has some weak cough suppressant action. Caffeine is a stimulant which acts to enhance the analgesic effects of paracetamol.

Maxilief Effervescent Tablets are used for the relief of headache, including migraine, musculoskeletal pain, toothache, backache, common cold, influenza and menstrual pain.

Codeine can be used in children over 12 years of age for the short-term relief of acute moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MAXILIEF EFFERVESCENT TABLETS**

#### **Do not take Maxilief Effervescent Tablets**

- If you are allergic to paracetamol, codeine, caffeine or any of the other ingredients of this medicine (listed in section 6).
- If you are under 12 year old.
- If you have acute asthma.
- If you suffer from breathing difficulties.
- **WITH ANY OTHER PARACETAMOL OR CODEINE CONTAINING PRODUCTS.**
- 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.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Maxilief Effervescent Tablets

- If you suffer from any liver or kidney disorder
- If you are pregnant, planning to become pregnant or breast-feeding
- If you have a bowel disorder
- If you have prostate problems
- If you have heart or blood pressure problems
- If you have recently had gall bladder surgery or a similar operation.
- If you are taking other medicines affecting liver function
- If you have Glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency)
- If you have haemolytic anaemia (abnormal breakdown of red blood cells)
- If you have glutathione deficiency
- If you are dehydrated or are suffering from chronic malnutrition
- If you weigh less than 50kg
- If you are elderly
- If you have Chronic alcoholism

If you are an older person you may be more sensitive to the effects of Maxilief Effervescent Tablets.

Maxilief Effervescent Tablets contain codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days, unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

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.

#### Adolescents older than 12 years of age

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children. Maxilief is not recommended in adolescents with compromised respiratory function for the treatment of cold.

### **Other medicines and Maxilief Effervescent Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your treatment can be affected if Maxilief Effervescent Tablets are taken with certain other medicines.

It is especially important to consult your doctor if you are already being treated with any of the following medicines:

- Metoclopramide or domperidone (for nausea and vomiting)

- Cholestyramine (for lowering blood cholesterol)
- Anticoagulants (used to prevent blood clotting, e.g. warfarin)
- Monoamine oxidase inhibitors (for depression, e.g. moclobemide)
- Tricyclic antidepressants (e.g. amitriptyline)
- Medicines which help you sleep or any other medication that makes you drowsy
- Medicines that you have bought yourself such as cough/cold remedies and other painkillers. These may contain paracetamol and/or codeine and must not be taken while you are taking Maxilief Effervescent Tablets.
- 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.

Concomitant use of Maxilief Effervescent Tablets 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 Maxilief Effervescent Tablets 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.

#### **Maxilief Effervescent Tablets with food and drink**

Do not consume excessive quantities of tea, coffee or cola whilst taking these tablets. You should avoid alcohol when taking Maxilief Effervescent Tablets.

#### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicines.

Maxilief Effervescent Tablets contain codeine. Do not take Maxilief while you are breast-feeding. Codeine and morphine passes into breast milk.

#### **Driving and using machines**

If you feel drowsy when you start taking this medicine, do not drive or operate machinery until this effect wears off.

#### **Maxilief Effervescent Tablets contain sorbitol (E420) and sodium**

This medicine contains 50 mg sorbitol in each 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.

This medicine contains 388 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 19.4% of the recommended maximum daily dietary intake of sodium for an adult. The maximum recommended daily dose of this medicinal product contains 3.104g sodium (found in table salt). This is equivalent to 155% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need Maxilief Effervescent Tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

### **3. HOW TO TAKE MAXILIEF EFFERVESCENT TABLETS**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

**Adults (including older people):** Take two tablets dissolved in a glass of water three or four times in a 24 hour period as required. The dose should not be repeated more frequently than every six hours. Do not take more than 8 tablets in any 24 hour period.

The maximum daily dose of paracetamol should not exceed 60 mg / kg / day (up to four tablets in 24 hours) in the following situations:

- weight of less than 50 kg
- dehydration
- chronic malnutrition

Experience has indicated that normal adult dosage is usually appropriate in the elderly. However in frail, immobile, elderly subjects or in elderly patients with renal or hepatic impairment, a reduction in the amount or frequency of dosing may be appropriate.

Use in renal impairment:

In mild to moderate kidney impairment, the recommended dose is one tablet every 6 hours.

In severe kidney impairment, the recommended dose is one tablet every 8 hours.

Use in liver impairment:

In case of problems with your liver please consult your doctor. Your doctor may decide to reduce the dose.

In chronic alcoholism, a maximum of four tablets in 24 hours should not be exceeded.

**Children aged 16 to 18 years:** Take one to two tablets dissolved in a glass of water every six hours when necessary, up to a maximum of four doses in a 24 hour period as required. The dose should not be repeated more frequently than every six hours.

**Children aged 12 years to 15 years:** Take one tablet dissolved in a glass of water every six hours when necessary, up to a maximum of four doses in a 24 hour period as required. The dose should not be repeated more frequently than every six hours.

**Use in children aged less than 12 years:** Maxilief Effervescent Tablets should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

**NOT SUITABLE FOR CHILDREN UNDER 12 YEARS OF AGE.**

**DO NOT EXCEED THE STATED DOSE.**

Codeine should be used at the lowest effective dose for the shortest period of time. 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.

Consult your doctor if there is no improvement.

Prolonged use except on the doctor's advice may be harmful.

This product should only be used when clearly necessary.

**If you take more Maxilief Effervescent Tablets than you should**

The symptoms of overdose may include: pallor, nausea, vomiting, difficulty breathing, loss of appetite, abdominal pain, nervousness, insomnia, flushed face, restlessness, muscle twitching, increased need to urinate, increased or irregular heart beat, gastrointestinal bleeding, involuntary movement or periods of inexhaustibility.

**YOU SHOULD CONTACT YOUR DOCTOR OR NEAREST HOSPITAL CASUALTY DEPARTMENT IMMEDIATELY IF YOU TAKE TOO MUCH, EVEN IF YOU FEEL WELL, BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE.**

Some patients may be at increased risk of liver damage:

Risk factors include;

- Patients with liver disease
- Elderly patients
- Young children
- Patients receiving long-term treatment with particular medicines: carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Patients who regularly consume alcohol in excess of recommended amounts
- Patients with glutathione depletion e.g. eating disorders, cystic fibrosis, HIV infection, starvation, chronic illness

#### **If you forget to take Maxilief Effervescent Tablets**

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

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.

**This medicine may sometimes cause allergic reactions such as skin rash. These effects should go away once you stop taking the medicine.**

Codeine may cause constipation, nausea, vomiting, light-headedness, confusion, retention of urine, dizziness and drowsiness. However these side effects are dependent on the dose and are very rare at the recommended dose for Maxilief Effervescent Tablets.

You may experience problems with your blood which means that you may bleed or bruise easily (known as thrombocytopenia) or which makes it more likely that you may get an infection (known as agranulocytosis). If you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting, or if you have previously experienced breathing problems with aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product, stop taking this medicine and tell your doctor immediately. Taking any type of pain reliever for headaches for a long period of time can make them worse. If this situation is experienced or suspected, stop taking this medicine and talk to your doctor.

Very rarely, some of the following side effects may occur:

- allergic reactions such as skin rash or itching, sometimes with breathing problems, or swelling of the lips, tongue, throat or face.
- skin rash or peeling of the skin which may be accompanied by mouth ulcers. Very rare cases of serious skin reactions have been reported.

If you are concerned about these or any other unwanted effects while taking Maxilief Effervescent Tablets, stop taking the tablets and tell your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **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:

HPRRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. HOW TO STORE MAXILIEF EFFERVESCENT TABLETS**

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 and the laminate strips after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from 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. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Maxilief Effervescent Tablets contain:**

The active substances are paracetamol 500 mg, codeine phosphate hemihydrate 8 mg and caffeine 30 mg.

The other ingredients are sorbitol (E420), saccharin sodium (E954), sodium hydrogen carbonate (E500), povidone, sodium laurilsulfate, citric acid anhydrous (E330), sodium carbonate (E500) and dimeticone.

### **What Maxilief 500/8/30 mg Effervescent Tablets look like and contents of pack:**

Maxilief 500/8/30 mg Effervescent Tablets are flat, bevelled-edged, white tablets scored on one side and plain on reverse.

Pack sizes: 12, 24, 60 & 100 tablets (60 and 100 tablets are for dispensing purposes only)  
Not all pack sizes may be marketed.

**Marketing Authorisation holder:** Clonmel Healthcare Ltd,  
Clonmel, Co. Tipperary, Ireland.

**Manufacturers:** Clonmel Healthcare Ltd,  
Clonmel, Co. Tipperary, Ireland.

A. Nattermann & Cie. GmbH,  
Nattermannallee 1, 50629 Cologne, Germany

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