

MIGRALEVE®

Paracetamol, Codeine phosphate & Buclizine hydrochloride

- For the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone such as migraine attacks, including the symptoms of migraine headache, nausea and vomiting.
- You should only take this product for a maximum of three 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 three 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 three days it can make them worse.
- This medicine is for use by adults and children aged 12 years and over.

Now read this whole leaflet carefully before you use this medicine.

Keep the leaflet: you might need it again.

1 What the medicine is for

For the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone such as migraine attacks, including the symptoms of migraine headache, nausea and vomiting.

There are two types of MIGRALEVE® tablet available:

- **MIGRALEVE® Pink** tablets
- **MIGRALEVE® Yellow** tablets

They are available separately or together in one pack.

MIGRALEVE® Pink tablets contain paracetamol and codeine which eases pain and buclizine which helps relieve nausea and vomiting. The Pink tablets therefore treat all the symptoms of migraine. If taken at the first sign of a migraine, MIGRALEVE® Pink tablets can prevent an attack from developing.

MIGRALEVE® Yellow tablets contain paracetamol and codeine for the treatment of pain and relief of continuing migraine symptoms. They should always be taken after the first dose of MIGRALEVE® Pink tablets.

Codeine 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. This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

2 Before taking this medicine

- This medicine contains **paracetamol**. Do not take anything else containing paracetamol while taking this medicine.
 - Do not take for longer than three days at a time.
 - Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
 - Taking a painkiller for headaches too often or for too long can make them worse.
- This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use this medicine...

- Unless your migraines have been **diagnosed by a doctor**.
- If you have taken any other painkillers in the last four hours.
- If you are allergic to paracetamol, codeine or buclizine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking other medicines containing **paracetamol**.
- In **children under 12 years of age**.
- In children and adolescents (0-18 years of age) after removal of their tonsils or adenoids for obstructive sleep apnoea syndrome.
- If you have recently developed shallow breathing.
- If your bowel is obstructed or does not work properly.
- If you have a head injury or raised pressure in your skull (may cause painful eyes, change in vision or headache behind the eyes).
- If you know that you metabolise codeine into morphine very rapidly.
- If you are breastfeeding.

If any of these apply to you, **get advice from a doctor or pharmacist without using MIGRALEVE®.**

! Talk to your doctor or pharmacist...

- If you suffer from **liver or kidney disease**.
- If you suffer from **alcoholic liver disease or alcoholic dependence**.
- If you are taking any other **medicines**.
- If you have **closed angle glaucoma** (increased pressure in the eye).
- If you have **difficulty passing water or unable to pass water**.
- If you have **prostate disease**.
- If you suffer from fits.
- If you suffer from asthma or breathing problems or other lung disease.

During treatment with this medicine, tell your doctor straight away if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic).
- A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).
- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.
 - you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Other medicines and Migraleve

Please inform your doctor or pharmacist if you are taking:

- **metoclopramide or domperidone** (used to treat **nausea and vomiting**)
- **cholestyramine** (used to treat **high cholesterol**)
- if you are taking or have taken in the last two weeks, **Monoamine Oxidase Inhibitors** (MAOIs such as moclobemide, phenelzine, tranylcypromine or selegiline) for **depression** or other conditions.
- **anticoagulants** (drugs that **thin the blood**, such as warfarin)
- **anticonvulsants** such as carbamazepine, phenytoin, fosphenytoin, phenobarbital or primidone (used to treat **epilepsy**)
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- **antimuscarinic drugs e.g. atropine** (drug given **prior to surgery** and for some **eye and bowel conditions**)
- Drugs affecting the brain:
 - drugs used to **decrease anxiety or to help you sleep** (e.g. **benzodiazepines** or **barbiturates**)
 - **antidepressants** (e.g. **tricyclic antidepressants**)
 - drugs used for **mental conditions causing delusions or hallucinations** (e.g. **phenothiazines**)

turn over ►

- *General anaesthetics*
- *Muscle relaxants*
- Other painkillers containing *paracetamol* or *codeine* or products similar to codeine e.g. *tramadol*, *morphine*
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

If you are not sure about the medicine you are taking, show the pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist**.

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.

Sleep-related breathing disorders

Migraleve can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of this medicine can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

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The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted this medicine if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking this medicine).

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used in children and adolescents after removal of their tonsils or adenoids for 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.

If you are pregnant or breastfeeding

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant.

Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk.

Special warnings about drowsiness

Driving and using machines

- The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while 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 while taking this medicine.

3 How to take this medicine

Check the tables below to see how much medicine to take.

- For oral use only. Swallow the tablets with a glass of water.
- Do not take less than four hours after taking other painkillers.
- Always start with MIGRALEVE® Pink tablets.
- Do not take more than the stated dose shown below.
- This medicine should be used for 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.

Children under 12 years

Do not give to children below the age of 12 years, due to the risk of severe breathing problems.

Children 12 – 15 years

Age	Dose
Children 12 – 15 years	Swallow 1 MIGRALEVE® Pink tablet at the first sign of a migraine attack. If the migraine persists, then take 1 MIGRALEVE® Yellow tablet 4 hours after the Pink dose and then every 4 hours.
	<ul style="list-style-type: none"> ■ Do not take more than 4 tablets (1 pink and 3 yellow) in a 24 hour period. ■ If symptoms persist for more than 3 days or get worse, stop use and talk to your healthcare professional.

i Adults and Children 16 years and over

Age	Dose
Adults and children 16 years and over	Swallow 2 MIGRALEVE® Pink tablets at the first sign of a migraine attack. If the migraine persists, then take 2 MIGRALEVE® Yellow tablets 4 hours after the Pink dose and then every 4 hours.

- Do not take more than 8 tablets (2 pink and 6 yellow) in a 24 hour period.
- If symptoms persist for more than 3 days or get worse, stop use and talk to your healthcare professional.

! **If anyone has too much**
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.

! **If you forget to take the medicine**
You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose. **Remember that you can only take one MIGRALEVE® Pink dose in any 24 hour period.**

! **If you stop taking this medicine**
This medicine contains codeine and can cause addiction if you take it continuously for more than three 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

MIGRALEVE® can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using the medicine and tell your doctor straightaway:

- Allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.

- Very rare cases of serious skin reactions have been reported. Symptoms may include: skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.
- Signs of codeine toxicity e.g. confusion, shallow breathing or extreme sleepiness.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). This side effect has a frequency of "not known" which means it cannot be estimated from the available data.

Other effects which may occur include:

Very common:

- Feeling sick, sleepiness (although desire to sleep can be a symptom of migraine).
- Headache.
- Reddening and flushing of face.

Common:

- Constipation, being sick, dry mouth.
- Dizziness, increased sweating.

Uncommon:

- Feeling happy.
- Rash.

Not known:

- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.
- Addiction or withdrawal symptoms (e.g., tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly).
- Difficulty in passing urine.
- Problems with movements and coordination.
- Kidney problems.
- Loss of appetite, indigestion, abdominal pain or discomfort.
- Itching and hives.
- Liver problems.
- Blurred vision.
- Breathing difficulty, thickened mucus.
- Hypothermia.

- Tiredness.
- Twitching.
- Fits.
- Sensation of spinning.
- Decrease in sex hormones.
- Adrenal glands not working properly (may cause weakness, tiredness, weight loss, low blood pressure).

People who use medicines containing paracetamol every day for a long time could get certain side effects, including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems, but liver function tests may be affected.

How do I know if I am addicted?

If you take the 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 unwell but you feel better when you start taking the medicine again.

Reporting of side-effects:

If you get any side-effects, talk to your doctor, pharmacist or nurse. 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 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.

5 Storing this medicine

There are no special storage instructions for this medicine. Store this medicine in a safe and secure storage space, where other people cannot access it. Keep 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.

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's in this medicine?

The active ingredients in each MIGRALEVE® Pink tablet are: Paracetamol DC 96% 520 mg equivalent to Paracetamol 500 mg, Codeine phosphate 8 mg and Buclizine hydrochloride 6.25 mg.

Other ingredients are: magnesium stearate, colloidal anhydrous silica, stearic acid, pregelatinised maize starch, gelatin, hypromellose, macrogol, E127 (erythrosine), aluminium oxide and E171 (titanium dioxide).

The active ingredients in each MIGRALEVE® Yellow tablet are: Paracetamol DC 96% 520 mg equivalent to Paracetamol 500 mg and Codeine phosphate 8 mg.

Other ingredients are: magnesium stearate, colloidal anhydrous silica, stearic acid, pregelatinised maize starch, gelatin, hypromellose, macrogol, E104 (quinoline yellow), aluminium oxide, E171 (titanium dioxide) and E172 (iron oxide yellow).

What the medicine looks like

There are two types of MIGRALEVE® tablets available: MIGRALEVE® Pink and MIGRALEVE® Yellow. These are film coated tablets which are available separately or together in one pack.

Packs on sale in your Pharmacy

MIGRALEVE®: 12 tablet pack containing
8 **MIGRALEVE® Pink** and 4 **MIGRALEVE® Yellow** tablets

MIGRALEVE®: 24 tablet pack containing
16 **MIGRALEVE® Pink** and 8 **MIGRALEVE® Yellow** tablets

MIGRALEVE® Pink: packs of 12 and 24 tablets

MIGRALEVE® Yellow: packs of 24

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