

Package leaflet: Information for the patient

MIGRALEVE®

Paracetamol DC 96% 520mg, Codeine phosphate 8mg, Buclizine hydrochloride 6.25mg film- coated tablets

This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

- 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.
- 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

This medicine has been prescribed to you 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.

It contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

It also contains paracetamol, another analgesic to relieve pain.

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.

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 directed by your prescriber.
 - 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.

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).

Other medicines and this medicine

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**)
- *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*)
- *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

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Migraleve® to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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 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

Do not take Migraleve® if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Migraleve® during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Migraleve® while you are breastfeeding as codeine passes into breast milk and will affect your baby.

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.

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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 doctor. 	

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.
<ul style="list-style-type: none"> ▪ 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 doctor. 	

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

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any

unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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:

- Acute inflammation of the pancreas in patients who have had a cholecystectomy (gall bladder removal).
- Dependence and addiction (see section "How do I know if I am addicted?")
- 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.

Drug Withdrawal

When you stop taking Migraleve, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Migraleve®, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
 - You feel you need to use more than the recommended dose
 - You are using the medicine for reasons other than prescribed
 - When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again
- If you notice any of these signs, it is important you talk to your prescriber.

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. 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, pregelatinized 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 available only on prescription from your Doctor

MIGRALEVE®: 48 tablet pack containing 32 **MIGRALEVE® Pink** and 16 **MIGRALEVE® Yellow** tablets

MIGRALEVE® Pink: packs of 48 tablets

Please Note: Because MIGRALEVE® packs contain both MIGRALEVE® Pink and MIGRALEVE® Yellow tablets, a double prescription charge must be made.

Product Licence holder: McNeil Products Ltd, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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