

MIGRALEVE®

film coated tablets

MIGRALEVE® Pink

Paracetamol 500 mg, Codeine phosphate 8 mg,
Bucizine hydrochloride 6.25 mg

MIGRALEVE® Yellow

Paracetamol 500 mg,
Codeine phosphate 8 mg,

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to take MIGRALEVE® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side-effects get serious or if you notice any side-effects not listed in this leaflet, please talk to your doctor or pharmacist.

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1 What MIGRALEVE® is and what it is used for

MIGRALEVE® is a medicine which is used for the treatment of 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.

MIGRALEVE® can be used in children over 12 years of age for the short term relief of moderate pain not relieved by other pain killers such as paracetamol or ibuprofen alone.

MIGRALEVE® contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

2 Before you take MIGRALEVE®

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 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**.
- For pain relief in children and adolescents (0-18 years of age) after removal of

their tonsils or adenoids for obstructive sleep apnoea syndrome.

- 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®.**

⚠ Take special care...

- If you suffer from **liver or kidney disease**.
- If you have Gilbert's syndrome (familial non-haemolytic jaundice).
- If you have a condition called Glucose- 6- phosphate dehydrogenase deficiency.
- If you have haemolytic anaemia.
- If you have glutathione deficiency.
- If you are dehydrated or chronically malnourished.
- If you weigh less than 50kg.
- In elderly patients, the normal adult dosage is usually appropriate. However, in frail, immobile, elderly patients or in elderly patients with kidney or liver problems, a reduction in the amount or frequency of dosing may be appropriate and you should ask your doctor or pharmacist for advice.
- If you suffer from **alcoholic liver disease or alcohol dependence**.
- 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 **head injuries or raised pressure in the skull** (may cause painful eyes, changes in vision or headache behind the eyes).
- If you suffer from **asthma or breathing problems or other lung disease**.

⚠ Taking other medicines...

Talk to your doctor or pharmacist...

- If you are taking any other **prescribed medicines**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MOAIs).
- If you are taking any other medicine including:
 - *metoclopramide* or *domperidone* (used to treat **nausea and vomiting**).
 - *cholestyramine* (used to treat **high cholesterol**).
 - 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.
 - *anticoagulants* (drugs that **thin the blood**, such as warfarin).
 - *anticonvulsants* (used to treat **epilepsy**).
 - Medicines that can affect liver function.
 - *oral contraceptive steroids* (**birth control pill**).
 - 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 affecting serotonin or noradrenaline levels, *trazodone*).
 - drugs used for **mental conditions causing delusions or hallucinations** (e.g. *phenothiazines*).
 - *methadone* (assistance with drug withdrawal).
- *Muscle relaxants*
- Other painkillers containing *paracetamol* or *codeine* or products similar to codeine e.g. *tramadol*, *morphine*

■ If you are not sure about the medicine you are taking.

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

⚠ If you are pregnant or breastfeeding

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant. Do not take this medicine while you are breastfeeding. Codeine and morphine pass into breast milk.

⚠ Special warnings about this medicine

- 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.
- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. If you need to use this medicine for more than three days at a time, see your doctor, pharmacist or healthcare professional.
- When you stop taking it you may feel restless and irritable.
- Hyperalgesia may occur with the use of opioids or as a side effect during withdrawal, particularly with high doses. An unexplained increase in pain, or increased levels of pain can occur with increasing opioid dosages. If you are on any opioid for pain, consult a physician before using this product.
- Talk to your doctor or pharmacist if you have any breathing problems whilst sleeping.
- **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 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.

⚠ Driving and using machines

MIGRALEVE® Pink tablets may cause drowsiness. If affected, do not drive or operate machinery.

⚠ Taking with food or drink

- Avoid alcoholic drink.

3 How to take MIGRALEVE®

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

- Always start with MIGRALEVE® Pink tablets.
- Swallow the tablets with a glass of water.
- Do not take more than the stated dose shown below.
- Do not take for more than 3 days. If you need to use this medicine for more than 3 days you must speak to your doctor or pharmacist.

i Children under 12 years

This medicine is not suitable for children under 12 years of age.

i Children 12-18 years

Age Dose

Children Swallow 1 MIGRALEVE® Pink tablet at the first sign of a migraine attack.
12-15 If the migraine persists, then take 1 MIGRALEVE® Yellow tablet 6 hours after
years the Pink dose and then every 6 hours.

- Do not take more than 4 tablets (1 pink and 3 yellow) in a 24 hour period.

turn over ►



Age	Dose
Children 16-18 years	Swallow 1-2 MIGRALEVE® Pink tablets at the first sign of a migraine attack. If the migraine persists, then take 1-2 MIGRALEVE® Yellow tablets 6 hours after the Pink dose and then every 6 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.

i Adults and the elderly

Age	Dose
Adults and the elderly	Swallow 1-2 MIGRALEVE® Pink tablets at the first sign of a migraine attack. If the migraine persists, then take 1-2 MIGRALEVE® Yellow tablets 4-6 hours after the Pink dose and then every 4-6 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

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. Take this leaflet and any remaining tablets with you.

! 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 6 hours ago for children 12-18 years and at least 4-6 hours ago for adults and the elderly. Do not take a double dose. Remember that you can only take one MIGRALEVE® Pink dose in any 24 hour period.

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:

- Allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rashes 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.

Other effects which may occur include:

Very common:

- Feeling sick, sleepiness (although desire to sleep can be a symptom of migraine).

Common:

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

Uncommon:

- Feeling happy.
- Indigestion, abdominal pain or discomfort.
- Itching, rash, hives, reddening or flushing of the face.

Frequency unknown:

- Agitation, 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).
- Breathing difficulty.

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.

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 HPRA Pharmacovigilance, website: www.hpra.ie.

You can also report side effects directly in Malta via ADR Reporting at: www.medicinesauthority.gov.mt/adrportal.

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

5 How to store MIGRALEVE®

Do not store above 30°C.

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 blister after 'Exp'.

The expiry date refers to the last date 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 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 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® Pink	packs of 12 tablets

Product Authorisation holder: JNTL Consumer Health I (Ireland) Ltd. Block 5, High Street, Tallaght, Dublin 24, Ireland.

Manufacturer: JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

MIGRALEVE® is a registered trade mark.

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7 Facts about Migraine

What is Migraine?

Migraine is a common condition, affecting about 10% of the population. It is more common in women than men.

Migraine consists of a headache, often on one side, accompanied by one or more of the following symptoms:

- An upset stomach, with nausea (feeling sick) or vomiting (being sick).
- Sensitivity to light, sound or smells.
- Visual disturbance such as flashing or flickering lights, blind spots or the inability to focus.

This invariably occurs before the migraine headache and is known as the aura.

Symptoms of migraine can last from a few hours to 2-3 days, but an attack is usually over within 24 hours.

Migraine is a varied condition and can seriously disrupt your life for the duration of the attack. However there is complete freedom from symptoms between attacks.

The frequency of attacks is very variable, with some sufferers experiencing only one or two attacks each year, whilst others may at times be affected more than once a week.

Many sufferers can identify factors which trigger or aggravate a migraine attack, such as:

- Physical (over-exertion, too much or too little sleep).
- Psychological (anxiety, depression, stress, shock, excitement).
- Diet (foods such as chocolate, cheese, alcohol, irregular or missed meals).
- Hormonal/physiological (menstruation, oral contraceptives, menopause, high blood pressure).
- Other factors (flickering light, bright light/glare, VDU/TV screen, noise, strong smells).

As soon as you realise a migraine has already started, or is about to start, take MIGRALEVE® Pink tablets: if taken early enough they can prevent a migraine attack from developing. Please see 'Section 3' for appropriate dosage.

Migraine in Children

Between the ages of 5 and 15, one child in nine suffers from attacks of migraine which they may describe as a 'sick headache'. The headache is accompanied by symptoms such as nausea, vomiting, stomach pain or food intolerance. Migraine in children does not differ in any essential way from migraine in adult life but headache symptoms may be less pronounced. Ensure the child does not miss meals or sleep and avoids foods known to trigger an attack. MIGRALEVE® Tablets are suitable for children over the age of twelve (see Section 2 'How to take this medicine') but is not recommended for younger children.

For further information, consult your doctor or pharmacist.