

Migraleve™

Paracetamol, Codeine & Bucizine

- 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 10 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.

2 Before taking this medicine

- 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 a painkiller for headaches for more than three days it can make them worse.
- If you have been prescribed this product do not take it for longer than directed by your doctor.

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 have ever had a **bad reaction** to Migraleve or any of its ingredients.
- If you are taking other medicines containing **paracetamol**.
- If it is for a **child under 10 years of age** unless this is under medical supervision.

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 are taking any other **prescribed medicines**.
- If you are taking any other medicines including:
 - *metoclopramide* or *domperidone* (used to treat **nausea and vomiting**)
 - *colestyramine* (used to treat **high cholesterol**)
 - *anticoagulants* (drugs that **thin the blood**, such as warfarin)

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

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 breast-feeding

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

Usually it is safe to take Migraleve while breast-feeding as the levels of the active ingredients of this medicine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels in their breast milk. If any of the following side effects develop in you or your baby, stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal and shallow or slow breathing.

! Special warnings about drowsiness

- These tablets may cause drowsiness.
If affected, do not drive or operate machinery.
Avoid alcoholic drink.

3 How to take this medicine

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

- Do not take less than four hours after taking other painkillers.
- 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 three days you must speak to your doctor or pharmacist.

i Children under 10 years

This medicine is not recommended for children under 10 years old unless this is given under medical supervision.

i Children 10 – 14 years

Age	Dose
Children 10 – 14 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.
■ 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, talk to your doctor.	

i Adults and Children 15 years and over

Age	Dose
Adults and children 15 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, 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 4 hours ago. **Do not** take a double dose. **Remember that you can only take one Migraleve Pink dose in any 24 hour period.**



Special warnings about addiction

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

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor or other healthcare professional.

Also you can help to make sure that medicines remain as safe as possible by **reporting any unwanted side-effects via the internet at www.yellowcard.gov.uk**; alternatively you can call **Freephone 0808 100 3352** (available between 10am-2pm Monday - Friday) or **fill in a paper form** available from your local pharmacy.

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 such as skin rashes, hives or itching, which can occur rarely.

Other effects which may occur include:

- Constipation.
- Drowsiness (although the desire to sleep can be a symptom of migraine).
- Taking a painkiller for headaches too often or for too long can make them worse.

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.

5 Storing this medicine

There are no special storage instructions for this medicine.

Keep the product out of the reach and sight of children.

Do not use after the end of the month shown as an expiry date on the packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to 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 Bucizine 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
24 tablet pack containing
16 **Migraleve Pink** and
8 **Migraleve Yellow** tablets
packs of 12 and 24 tablets
packs of 24

Migraleve Pink Migraleve Yellow

Packs available only on prescription from your Doctor

Migraleve

48 tablet pack containing
32 **Migraleve Pink** and
16 **Migraleve Yellow** tablets
packs of 48 tablets

Migraleve Pink

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, Maidenhead, Berkshire, SL6 3UG, UK.

Manufacturer: Janssen Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

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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.

For further information, consult your doctor or pharmacist.