Migraleve™

Paracetamol, Codeine & Buclizine

- 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 can be used on its own or in combination with other pain killers such as paracetamol.

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.

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 12 years of age**.
- 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

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 **prescribed medicines.**
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you have **closed angle glaucoma** (increased pressure in the eye).
- 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)
  - *antimuscarinic drugs e.g.:*
    - *atropine* (drug used to treat some **eye conditions** and occasionally **bowel conditions**)
    - *tricyclic antidepressants* (drugs to treat **mood disorders**)
  - *CNS depressants e.g.:*
    - *hypnotics* (**sleeping tablets** including barbiturates)
    - *sedatives* (drugs used to **produce calmness** or to **help you sleep**)
    - *tranquilisers* (drugs used to **relax muscles** or **decrease anxiety**)
    - *opioid analgesics* (drugs used to relieve pain eg. codeine, tramadol, morphine)
- If you have **difficulty passing water** (urinary retention).
- If you have **prostate disease.**
- If you drink **large amounts of alcohol**, you may be more open to the side effects of paracetamol.

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.**

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.

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.

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
These tablets may cause drowsiness. If affected do not operate machinery.

This medicine can affect your ability to drive.

Do not drive whilst taking this medicine until you know how this medicine affects you.

It may be an offence to drive when taking this medicine if your ability to drive safely is affected. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

There is further information for patients who are intending to drive in the UK - go to https://www.gov.uk/drug-driving-law.

Avoid alcoholic drink.

turn over ▶

spot = 12 x 2 centered in the margin of 14 mm

Distance between cutted line/middel of the spot = **83.6 mm**

Barcodes placed at 14 mm
Hight for bars : 10 mm

14

reading way

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 not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

Children under 12 years
This medicine should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Children 12 – 14 years

Age	Dose
Children 12 – 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.

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 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. These are very rare and not necessarily related to paracetamol.

Other effects which may occur include:
- Constipation.
- Itching.
- Sweating.
- Dry Mouth.
- Drowsiness (although the desire to sleep can be a symptom of migraine), nausea (feeling sick or queasy) and vomiting (being sick).
- Indigestion, pain or discomfort in the abdomen.
- Acute inflammation of the pancreas in patients who have had a cholecystectomy (gallbladder removal).
- Difficulty in passing urine.
- Headache, dizziness, problems with movements and coordination, upset stomach, thickened mucus and blurred vision.
- 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 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

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, Maidenhead, Berkshire, SL6 3UG, UK.
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McNeil Products Ltd.

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Johnson & Johnson	
Job Bag No.	14-0051
Version	4
Product	Migraleve (12s/24s/48s)
Description	Pil
Country	UK
Date	08/04/2014
Manufacturer	Val De Reuil
Software	Illustrator CS5

COLOURS:

BLACK | Rhodamine Red | PROFILE

SIZE:	Main body text (PIL's only)
145 x 210 mm	6.5 pts

A print out of this image should not be used for exact colour matching but to check if the layout, spelling, text and colour references are correct. Please check thoroughly.