

Migraleve™

- Migraleve is available in Pink and Yellow tablets which are taken at different stages of a migraine. Please go to section 3 for the full dosing instructions. *See section 3* ▶
- This medicine is used for the treatment of migraine attacks, including the symptoms of migraine headache, nausea and vomiting.
- This medicine is for use by adults and children aged 10 years and over.
- **Do not use this medicine:**
 - Unless your migraines have been **diagnosed by a doctor**. *See section 2* ▶
 - If you are already taking medicines containing **paracetamol**. *See section 2* ▶
 - If you have had a **bad reaction** to Migraleve or any of the ingredients in it. *See section 6* ▶
 - If it is for a **child under 10 years old**. *See section 3* ▶
- **Speak to your doctor:**
 - If you need to use this medicine for more than 3 days at a time.
 - If you suffer from **liver or kidney disease**. *See section 2* ▶
 - If you are **pregnant**. *See section 2* ▶
 - If you are taking other **prescribed medicines**. *See section 2* ▶
- **Follow the dosage instructions carefully.** Children and adults need different amounts. *See section 3* ▶

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

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.

2 Before taking this medicine

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 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 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 breast-feeding

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

! Special warnings about this medicine

- If you need to use this medicine for more than three days at a time, see your doctor, pharmacist or health care professional. However if you have been prescribed this product do not take it for longer than directed.
- Taking codeine regularly for a long time can lead to addiction, which might make you feel restless and irritable when you stop taking the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

! Special warnings about drowsiness

- Migraleve Pink 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.

- Always start with Migraleve Pink tablets.
- Swallow the tablets with a glass of water.
- Do not take more than the stated dose shown below.

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. **turn over** ▶

! 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.**

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 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 codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

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.

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 |
| | 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.

Manufacturer: Gödecke GmbH, Mooswaldallee 1, 79090, Freiburg, Germany.

This leaflet was revised December 2007.

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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.

Contact our advisory Bureau if you require any literature about migraine: Johnson and Johnson, The Braccans, London Road, Bracknell, Berkshire, RG12 2AT; 01344 864042.



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