

PATIENT INFORMATION LEAFLET

Please read this carefully before you take Migraleve. Keep this leaflet - you may wish to read it again.

About Migraleve

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

Each Migraleve Pink tablet contains: 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).

Migraleve Yellow

Each Migraleve Yellow tablet contains: 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).

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 12 and 24 tablets

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 packs of 48 tablets

Please Note: Because Migraleve packs contain both Migraleve Pink and Migraleve Yellow

tablets, a double prescription charge must be made.

The Product Licence holder is Pfizer Consumer Healthcare, Eastleigh, Hampshire. SO53 3ZQ. The manufacturer is: Gödecke GmbH, Mooswaldallee 1, 79090, Freiburg, Germany.

Treating Migraine

Migraleve is for the treatment of migraine attacks, including the symptoms of migraine headache, nausea and vomiting.

Migraleve Pink tablets 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 provide relief for continuing migraine symptoms. They should always be taken <u>after</u> the first dose of Migraleve Pink tablets.

Before taking Migraleve

Consult your doctor or pharmacist before taking this medicine because it may not be suitable for you if:

- · you are pregnant.
- · you suffer from high blood pressure, liver or kidney disease.

Do not use

- if you are taking medicines containing paracetamol or medicines prescribed by your Doctor.
- in children under 10 years of age except under medical supervision.
- if you are allergic to any of the ingredients in Migraleve.

Precautions

- · If symptoms persist, consult your doctor.
- Migraleve tablets contain potent ingredients and should not be taken continuously for extended periods without the advice of a doctor.
- · Do not exceed the stated dose.
- Migraleve Pink tablets only: may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.
- · Contains paracetamol.

How to take your medicine Always start with Migraleve Pink tablets

Adults:

- 2 Migraleve Pink tablets to be swallowed at the first sign of a migraine attack.
- If the migraine persists, then take 2 Migraleve Yellow tablets every 4 hours after the Migraleve Pink dose.
- Do not take more than 8 tablets (2 pink and 6 vellow) in a 24 hour period.

Children 10-14 years:

- 1 Migraleve Pink tablet to be swallowed at the first sign of a migraine attack.
- If the migraine persists, then take 1 Migraleve Yellow tablet every 4 hours after the Migraleve Pink dose.
- Do not take more than 4 tablets (1 pink and 3 yellow) in a 24 hour period.
- Do not give to children under 10 years of age except under medical supervision.

You should take your tablets with a drink of water.

If you take too many tablets

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.

Side-effects

Rarely, allergic reactions may occur, such as skin rashes, hives or itching. Sometimes constipation or drowsiness may occur. However, the desire to sleep can be a symptom of migraine.

If you experience any side-effects, or are not sure about anything, contact your Doctor or Pharmacist.

Storing Migraleve

- · Keep your medicine where children cannot reach it.
- Do not use your medicine if the pack is damaged, or after the expiry date on the pack.

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.

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 us if you require any literature about migraine, including specifically migraine in teenagers and a guide for parents of children with migraine.

REMEMBER

This leaflet does not contain the complete information about your medicine. If you have any queries or are not sure about anything ask your Doctor or Pharmacist who have access to additional information.