Patient Leaflet According to the Pharmacists' Regulations (Preparations), 1986
This medicine requires a physician's prescription

Migraleve

Tablets

Composition:
Each tablet contains:

Buclizine Hydrochloride	6.25 MG
Codein Phosphate	8 MG
Paracetamol	500 MG

See article 6 – "Additional Information" for a list of the inactive ingredients in this preparation.
Read the entire leaflet carefully before using your medicine.
This leaflet contains essential information about the medicine.
For further questions, see your physician or pharmacist. This medicine was prescribed for you. Do not hand it to others. It might damage their health even if their physical condition seems similar to yours.

- Do not use this medicine for more than three days. If more is required consult your physician or pharmacist first.
- This medicine contains codeine and as such extended use may cause dependence. After extended treatment withdrawal symptoms may appear after cessation of treatment.
- Headaches may intensify if this medication is used for headaches for more than 3 days.
- This medicine is not intended for use in children under the age of 12.

1. What is this medicine intended for?

This medicine is intended for the treatment of migraine attacks, including accompanying symptoms: headaches, nausea, vomiting.

Therapeutic group:
Buclizine Hydrochloride – Antihistamine
Codein Phosphate – opiate-based analgetic
Paracetamol – analgetic and antipyretic

2. Before using this medication

Do not use this medication:

- If you have not been diagnosed as suffering from migraine
- If you have taken another analgetic within the previous 4 hours
- If you are breast feeding.
- If you are concomitantly taking other medicines containing paracetamol
- If you are sensitive to Paracetamol or any other ingredient of this medicine.
- If you are under 12 years old
- If you know that you rapidly metabolize codeine (i.e. that you are an ultra-rapid metabolizer) and as such are at serious risk of developing a potentially severe side effect to codeine.
- If you are under 18 and have recently undergone a tonsillectomy or removal of the adenoids due to obstructive sleep apnea and as such are more susceptible to respiratory problems.

Specific warnings regarding the use of this medicine

- If you have in the past developed dermal side effects following the use of Paracetamol-containing Preparations, avoid using Paracetamol-containing preparations, so as to avoid any reoccurrence of such severe dermal effects.
- This preparation contains Paracetamol, which may cause liver damage:
  - When taken in higher dosage than recommended or for a prolonged period.
  - When alcoholic beverages are consumed during treatment.
  - When additional medicines that effect the liver function are taken simultaneously.
- Continuous use may cause dependence!
- Do not use this medicine often without consulting a physician.
- Do not take additional antipyretic and/or analgesic medicines or medicines used for common cold without first consulting a physician or a pharmacist, so as to avoid Paracetamol overdose/toxicity.
- Inform your physician before commencing treatment with this medicine if you are sensitive to any type of food or medicine

Consult a physician before commencing the treatment if you suffer or have suffered from impaired function of:

- The respiratory system (e.g. asthma)
- The heart and/or vascular system
- The eyes (e.g. glaucoma)
- The digestive system (e.g. ulcer)
- The thyroid gland
- The prostate gland
- The liver or suffered from liver disease
- The kidney/urinary tract

Before starting treatment with Migraleve inform your physician:

- If you are an alcoholic and/or suffer from a kidney disease as a result of alcohol use.
- If you are taking any other prescription medications.
- If within the past 14 days you have taken anti-depressants of the monoamine oxidase inhibitor (MAOI) group of compounds.
- If you suffer from acute angle glaucoma.
- If you are addicted to drugs (opiates or other medicines).
- If you suffer from urinary retention.
- If you have problems with the prostate gland.
- If you consume large amounts of alcohol as a result of which, may increase the likelihood of paracetamol side effects.

If you take or have taken other medicines recently
Including non-prescription medicines food additives and vitamins, inform your physician or pharmacist. In particular, inform your physician or pharmacist if you use any medicine from the following groups or have just finished treatment with one:

- Anti-emetics such as metclopramide or domperidone
- Cholestyramine (for the reduction of blood lipids)
- Anti-coagulants (such as Warfarin)
- Opiatic analgesics such as codeine, tramadol, morphine.
- Atropine.
- Aspirin and Salicylates.
- Medicines that effect the central nervous system (such as: sedatives, hypnotics, medicines for epilepsy)
- Anti-Depressants such as monoamine oxidase inhibitors (MAOI) or tricyclic antidepressants
- Non-steroidal anti-inflammatory drugs, such as diclofenac, ibuprofen, buprenorphine, naltrexone

Paracetamol usage and alcohol consumption
Do not consume alcoholic beverages while being treatment with Paracetamol, as it increases the risk of damage to the liver.

Pregnancy and breastfeeding
If you are pregnant consult your physician before commencing treatment.
Do not use this medicine if you are breastfeeding since codeine and morphine are excreted in mother's milk.

Driving and using machines
The use of this medicine may affect your alertness. Therefore, beware while driving a car or using dangerous machinery and performing any activity that requires being alert. As for children, warn them about cycling and playing close to traffic etc.

Consumption by Children
This medicine is suitable for adults and children over the age of 12 – see article 3.
Parents must inform the treating physician of any side effect and any additional medicine the child consumes.

3. How to use the medicine?
Always follow your physician's instructions.
The dosage and form of treatment shall be determined only by the physician. The usual dosage is:

Adults and children from the age of 15:
2 tablets when initial signs of migraine attack appear. Then, as required, 2 tablets every 4 hours up to a maximum of 8 tablets per day.

Children aged 12-14:
1 tablet when initial signs of migraine attack appear. Then, as required, 1 tablet every 4 hours up to a maximum of 4 tablets per day.

Do not exceed the recommended dose.

The form of use:
Do not chew or crush! The tablet may be halved.
Swallow the medicine with a glass of water.

If you have taken an overdose or if a child accidently swallowed the medicine, seek immediate medical assistance or immediately go to a hospital's emergency room and bring the medicine package with you. Do not induce vomiting unless explicitly instructed to do so by your physician! Even if you feel fine, it is essential to be treated immediately, **as severe damage to the liver might develop.**

Possible symptoms are nausea and vomiting, diarrhea, loss of appetite, stomachaches, swelling, excessive sweating, pain or sensitivity in the upper stomach, and it is possible that these events would not reflect the real extent of damage to the liver.
Do not take medicines in a dark place! Check the label and dosage every time you take a medicine.
If you wear glasses do so when taking medications.
Proceed with the treatment precisely as your physician recommended.

4. Side effects
Just as with any medicine, Migraleve may cause side effects to some users. Do not be concerned by the following list of side effects. It is likely that you would not suffer from any of them.
Severe side effects:
If they appear, immediately stop the treatment and contact a physician immediately:

- Hypersensitivity (rash or skin irritation, shortness of breath or difficulty breathing) or excess drowsiness, swelling especially of the face, tongue and throat, difficulty in swallowing.
- Unexplained tiredness, bruising or bleeding, unusual infection e.g. colds (in very rare cases and not necessarily attributed to Paracetamol).
- Paracetamol may, in rare cases, cause severe dermal diseases. Possible symptoms include: inflammation, rash, blisters, dermal damage. Severe dermal side effects may appear even if you have previously taken preparations that contained the ctive ingredient Paracetamol without suffering any adverse effects,.

If dermal side effects appear, immediately stop the treatment and contact a physician immediately.

Other side effects: dry mouth, constipation, drowsiness, in some cases a sensation of heat, problems with movement and coordination, sweating, itching, nausea, vomiting, gastrointestinal disorders, blurred vision, acute inflammation of the pancreas in those that have undergone surgery to remove the gallbladder, urinary retention.

Such events are normally transient as the body adjusts itself to the preparation.
In the event of a side effect becoming worse, or if you develop any side effect that was not mentioned in this leaflet, consult your physician immediately.

5. How to store this medicine?
Avoid poisoning! This medicine, as with all other medicines must be stored in a safe place and out of the reach of children and/or infants so as to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
Do not use the medicine after the expiration date (Exp. Date) that's printed on the package. The expiration date refers to the last day of the specified month.
Store in a dry place, below 25°C.

6. Additional Information
In addition to the active ingredients this medicine contains:
Inactive ingredients:
Magnesium stearate, colloidal silicon dioxide, stearic acid, starch pregelatinised, Erythrosine Lake code 15008 E 127, Opadry OY-1367 pink, Sterile water

Shape of the medicine and the contents of the package:
Oval pink tablet with the mark "MGE"

Manufacturer and license holder:
Manufacturer: Janssen-Cilag, Val De Reuil, France.
license holder: Manon Pharm Ltd. P.O.B. 39005 Tel-Aviv.

This leaflet was reviewed and approved by the Ministry of Health on 26.05.2015.
The medicine's registration number in the national Drug registry of the Ministry of Health: 107492916800