Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Migraleve (buclizine hydrochloride, paracetamol, codeine phosphate) Product Information:

Presentation:
Migraleve Pink: each pink, capsule-shaped, film-coated tablet is marked 'MGE' on one face, and contains buclizine hydrochloride 6.25mg, paracetamol 500mg, codeine phosphate 8mg. *Migraleve Yellow:* each yellow, capsule-shaped, film-coated tablet is marked 'MGE' on one face and contains paracetamol 500mg, codeine phosphate 8mg.

Uses:
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.
Dosage:
Adults & children 16 years and over: 2 Migraleve Pink tablets at first signs of a migraine, followed by 2 Migraleve Yellow tablets every 4 hours if symptoms persist. *Maximum dose in 24 hours:* eight tablets consisting of 2 Migraleve Pink tablets and 6 Migraleve Yellow tablets.
Children 12 to 15 years: 1 Migraleve Pink tablet at first signs of a migraine, followed by 1 Migraleve Yellow tablet every 4 hours if symptoms persist. *Maximum dose in 24 hours:* four tablets consisting of 1 Migraleve Pink tablet and 3 Migraleve Yellow tablets.
Contraindications:
This product is contraindicated in children under 12 years of age because of the risk of opioid toxicity. Hypersensitivity to the active substances (paracetamol, codeine phosphate, and/or buclizine hydrochloride) or to any of the excipients of this product is also a contraindication. Paediatric patients undergoing tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome, breastfeeding women, patients known to be CYP2D6 ultra-rapid metabolisers, patients with head injury or conditions with increased intracranial pressure, patients with acute respiratory depression, patients with obstructive bowel disorders, and patients at risk of paralytic ileus should not take Migraleve.
Precautions:
Migraine must be medically diagnosed before taking Migraleve and this product should not be taken continuously for extended periods, or for longer than 3 days without the advice of a doctor. Exercise caution in children with compromised respiratory function.
Codeine: Codeine is an opioid agent and therefore prolonged use or intake of high doses can cause tolerance, psychological and/or physical dependence and potential

for abuse. Please consult SmPC for full details including drug withdrawal syndrome and hyperalgesia. Codeine should be used with caution in patients with convulsive disorders, decreased respiratory reserve, such as bronchial asthma, pulmonary oedema, obstructive airways disease, renal and hepatic impairment, and when used concomitantly with other opioids, benzodiazepines or other central nervous system (CNS) depressants, monoamine oxidase inhibitors (MAOIs). Use for longer than 3 days can worsen headaches. Codeine may antagonise the effects of metoclopramide and domperidone on gastrointestinal motility. Concurrent use with other CNS depressants or opioid receptor agonists may cause additive CNS depression, respiratory depression and hypotensive effects. Possible interactions with MAOIs or who have used MAOIs in the previous two weeks.
Paracetamol: Hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Caution in chronic alcohol users, patients with severe renal or hepatic impairment and when used concomitantly with other paracetamol-containing products. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment, sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g., chronic alcoholism) who were treated with paracetamol at therapeutic doses for prolonged periods, or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, discontinue paracetamol immediately and close monitoring is recommended. Paracetamol may interact with drugs inducing hepatic microsomal enzymes. Its metabolism is possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, and primidone. Drug absorption may be increased by metoclopramide or domperidone, while it may be reduced by cholestyramine. Prolonged concomitant use with warfarin and other coumarins may increase anti-coagulant effect. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, while chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose.
Buclizine: Buclizine is a sedating antihistamine which may enhance sedative effects of CNS depressants and alcohol. It has an antimuscarinic action with other antimuscarinic drugs such as atropine, tricyclic antidepressants, and MAOIs. Therefore, it should be used with caution in prostatic hypertrophy, urinary retention, also where susceptibility exists to angle-closure glaucoma.

Effects on ability to drive and use machines:

May cause drowsiness. If affected do not operate machinery. This medicine can impair cognitive function and can affect a patient’s ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988.

Pregnancy and lactation:

This product should not be used in pregnancy unless benefits to the mother outweigh risk to foetus. There is inadequate evidence for the safety of codeine in human pregnancy. Neonatal exposure to codeine in utero can develop withdrawal syndrome after delivery. Paracetamol crosses the foetal circulation through the placenta as early as 30 minutes from ingestion and undergoes metabolism by conjugation with sulphate and increasingly with glutathione. Clinical data with use of buclizine in humans are not adequate to establish safety during pregnancy. Codeine is not recommended in breastfeeding women as codeine may be secreted in breastmilk and can cause respiratory depression in the infant. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breast-feeding. There are no data available relating to the safety of buclizine in breastfeeding mothers.

Side effects:

Prolonged use can cause codeine addiction and worsen headaches.
Very common: headache, somnolence, flushing, nausea.
Common: dizziness, constipation, dry mouth, vomiting, hyperhidrosis.
Uncommon: euphoric mood, rash, drug withdrawal syndrome.
Very rare: anaphylactic reaction (including skin rash), hypersensitivity.
Not known: blood disorder (including thrombocytopenia and agranulocytosis), drug dependence, psychomotor skills impairment, blurred vision, bronchospasm, dyspnoea, increased viscosity of bronchial secretion, respiratory depression, abdominal pain, dyspepsia, gastrointestinal disorder, pancreatitis acute (in patients with a history of cholecystectomy), liver injury, angioedema, dermatitis, erythema, fixed eruption, pruritus, urticaria, dysuria, nephropathy toxic, transaminases increased, high anion gap metabolic acidosis.
Please refer to Summary of Product Characteristics for detailed information
RRP (ex-VAT): 12 (8 Migraleve Pink, 4 Migraleve yellow): £7.59; 24 (16 Migraleve Pink, 8 Migraleve Yellow): £11.76
Legal category: 12 & 24: P
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
PL number: 15513/0105
Date of preparation: 27 Feb 2025

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Migraleve Pink (buclizine, paracetamol, codeine phosphate) Product Information:

Presentation:
Each pink, capsule-shaped, film-coated tablet is marked 'MGE' on one face, and contains buclizine hydrochloride 6.25mg, paracetamol 500mg, codeine phosphate 8mg.

Uses:
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.

Dosage:
Adults & children 16 years and over: 2 Migraleve Pink tablets at first signs of a migraine, followed by 2 Migraleve Yellow tablets every 4 hours if symptoms persist. *Maximum dose in 24 hours:* eight tablets consisting of 2 Migraleve Pink tablets and 6 Migraleve Yellow tablets.
Children 12 to 15 years: 1 Migraleve Pink tablet at the first signs of a migraine, followed by 1 Migraleve Yellow tablet every 4 hours if symptoms persist. *Maximum dose in 24 hours:* four tablets consisting of 1 Migraleve Pink tablets and 3 Migraleve Yellow tablets.

Contraindications:
This product is contraindicated in children under 12 years of age because of the risk of opioid toxicity. Hypersensitivity to the active substances (paracetamol, codeine phosphate, and/or buclizine hydrochloride) or to any of the excipients of this product is also a contraindication. Paediatric patients undergoing tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome, breastfeeding women, patients known to be CYP2D6 ultra-rapid metabolisers, patients with head injury or conditions with increased intracranial pressure, patients with acute respiratory depression, patients with obstructive bowel disorders, and patients at risk of paralytic ileus should not take Migraleve products.

Precautions:
Migraine must be medically diagnosed before taking Migraleve and this product should not be taken continuously for extended periods, or for longer than 3 days without the advice of a doctor. Exercise caution in children with compromised respiratory function.
Codeine: Codeine is an opioid agent and therefore prolonged use or intake of high doses can cause tolerance, psychological and/or physical dependence and potential for abuse. Please consult SmPC for full details including drug withdrawal syndrome and hyperalgesia. Codeine should be used with caution in patients with convulsive disorders, decreased respiratory reserve, such as bronchial asthma, pulmonary

oedema, obstructive airways disease, renal and hepatic impairment, and when used concomitantly with other opioids, benzodiazepines or other central nervous system (CNS) depressants, monoamine oxidase inhibitors (MAOIs). Use for longer than 3 days can worsen headaches. Codeine may antagonise the effects of metoclopramide and domperidone on gastrointestinal motility. Concurrent use with other CNS depressants or opioid receptor agonists may cause additive CNS depression, respiratory depression and hypotensive effects. Possible interactions with MAOIs or who have used MAOIs in the previous two weeks.
Paracetamol: Hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Caution in chronic alcohol users, patients with severe renal or hepatic impairment and when used concomitantly with other paracetamol containing products. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment, sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g., chronic alcoholism) who were treated with paracetamol at therapeutic doses for prolonged periods, or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, discontinue paracetamol immediately and close monitoring is recommended. Paracetamol may interact with drugs inducing hepatic microsomal enzymes. Its metabolism is possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, and primidone. Drug absorption may be increased by metoclopramide or domperidone, while it may be reduced by cholestyramine. Prolonged concomitant use with warfarin and other coumarins may increase anti-coagulant effect. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, while chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose.
Buclizine: Buclizine is a sedating antihistamine which may enhance sedative effects of CNS depressants and alcohol. It has an antimuscarinic action with other antimuscarinic drugs such as atropine, tricyclic antidepressants, and MAOIs. Therefore, it should be used with caution in prostatic hypertrophy, urinary retention, also where susceptibility exists to angle-closure glaucoma.

Effects on ability to drive and use machines:

May cause drowsiness. If affected do not operate machinery. This medicine can impair cognitive function and can affect a patient’s ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. For patient guidance please consult the SmPC.

Pregnancy and lactation:

This product should not be used in pregnancy unless benefits to the mother outweigh risk to foetus. There is inadequate evidence for the safety of codeine in human pregnancy. Neonatal exposure to codeine in utero can develop withdrawal syndrome after delivery. Paracetamol crosses the foetal circulation through the placenta as early as 30 minutes from ingestion and undergoes metabolism by conjugation with sulphate and increasingly with glutathione. Clinical data with use of buclizine in humans are not adequate to establish safety during pregnancy. Codeine is not recommended in breastfeeding women as codeine may be secreted in breastmilk and can cause respiratory depression in the infant. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. There are no data available relating to the safety of buclizine in breastfeeding mothers.

Side effects:

Prolonged use can cause codeine addiction and worsen headaches.
Very common: headache, somnolence, flushing, nausea.
Common: dizziness, constipation, dry mouth, vomiting, hyperhidrosis.
Uncommon: euphoric mood, rash, drug withdrawal syndrome.

Very rare: anaphylactic reaction (including skin rash), hypersensitivity.
Not known: blood disorder (including thrombocytopenia and agranulocytosis), drug dependence, psychomotor skills impairment, blurred vision, bronchospasm, dyspnoea, increased viscosity of bronchial secretion, respiratory depression, abdominal pain, dyspepsia, gastrointestinal disorder, pancreatitis acute (in patients with a history of cholecystectomy), liver injury, angioedema, dermatitis, erythema, fixed eruption, pruritus, urticaria, dysuria, nephropathy toxic, transaminases increased, high anion gap metabolic acidosis.
Please refer to Summary of Product Characteristics for detailed information
RRP (ex-VAT): 12: £6.95; 24: £11.04.
Legal category: 12 & 24: P
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
PL number: 15513/0103
Date of preparation: 27 Feb 2025

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Migraleve Yellow (paracetamol, codeine phosphate) Product Information

Presentation:
Each yellow, capsule-shaped, film-coated tablet is marked MGE on one face and contains paracetamol 500mg, codeine phosphate 8mg.

Uses:
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.

Dosage:
Adults and children 16 years and over: 2 Migraleve Pink tablets at first signs of a migraine, followed by 2 Migraleve Yellow tablets every 4 hours if symptoms persist. *Maximum dose in 24 hours:* eight tablets consisting of 2 Migraleve Pink tablets and 6 Migraleve Yellow tablets.
Children 12 to 15 years: 1 Migraleve Pink tablet at the first signs of a migraine, followed by 1 Migraleve Yellow tablet every 4 hours if symptoms persist. *Maximum dose in 24 hours:* four tablets consisting of 1 Migraleve Pink tablets and 3 Migraleve Yellow tablets.

Contraindications:
This product is contraindicated in children under 12 years of age because of the risk of opioid toxicity. Hypersensitivity to the active substances (paracetamol, codeine phosphate, and/or buclizine hydrochloride) or to any of the excipients of this product is also a contraindication. Paediatric patients undergoing tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome, breastfeeding women, patients known to be CYP2D6 ultra-rapid metabolisers, patients with head injury or conditions with increased intracranial pressure, patients with acute respiratory depression, patients with obstructive bowel disorders, and patients at risk of paralytic ileus should not take Migraleve products.

Precautions:
Migraine must be medically diagnosed before taking Migraleve and this product should not be taken continuously for extended periods, or for longer than 3 days without the advice of a doctor. Exercise caution in children with compromised respiratory function.
Codeine: Codeine is an opioid agent and therefore prolonged use or intake of high doses can cause tolerance, psychological and/or physical dependence and potential for abuse. Please consult SmPC for full details including drug withdrawal syndrome and hyperalgesia. Codeine should be used with caution in patients with convulsive disorders, decreased respiratory reserve, such as bronchial asthma, pulmonary oedema, obstructive airways disease, renal and hepatic impairment, and when used

concomitantly with other opioids, benzodiazepines or other central nervous system (CNS) depressants, monoamine oxidase inhibitors (MAOIs). Use for longer than 3 days can worsen headaches. Codeine may antagonise the effects of metoclopramide and domperidone on gastrointestinal motility. Concurrent use with other CNS depressants or opioid receptor agonists may cause additive CNS depression, respiratory depression and hypotensive effects. Possible interactions with MAOIs or who have used MAOIs in the previous two weeks.
Paracetamol: Hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Caution in chronic alcohol users, patients with severe renal or hepatic impairment and when used concomitantly with other paracetamol containing products. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment, sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g., chronic alcoholism) who were treated with paracetamol at therapeutic doses for prolonged periods, or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, discontinue paracetamol immediately and close monitoring is recommended. Paracetamol may interact with drugs inducing hepatic microsomal enzymes. Its metabolism is possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, and primidone. Drug absorption may be increased by metoclopramide or domperidone, while it may be reduced by cholestyramine. Prolonged concomitant use with warfarin and other coumarins may increase anti-coagulant effect. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, while chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose.

Effects on ability to drive and use machines:
May cause drowsiness. If affected do not operate machinery. This medicine can impair cognitive function and can affect a patient’s ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. For patient guidance please consult the SmPC.

Pregnancy and lactation:
This product should not be used in pregnancy unless benefits to the mother outweigh risk to foetus. There is inadequate evidence for the safety of codeine in human pregnancy. Neonatal exposure to codeine in utero can develop withdrawal syndrome after delivery. Paracetamol crosses the foetal circulation through the placenta as early as 30 minutes from ingestion and undergoes metabolism by conjugation with sulphate and increasingly with glutathione. Clinical data with use of buclizine in humans are not adequate to establish safety during pregnancy. Codeine is not recommended in breastfeeding women as codeine may be secreted in breastmilk and can cause respiratory depression in the infant. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding.

Side effects:
Prolonged use can cause codeine addiction and worsen headaches.
Very common: headache, somnolence, flushing, nausea.
Common: dizziness, constipation, dry mouth, vomiting, hyperhidrosis.
Uncommon: euphoric mood, rash, drug withdrawal syndrome.
Very rare: anaphylactic reaction (including skin rash), hypersensitivity.
Not known: blood disorder (including thrombocytopenia and agranulocytosis), drug dependence, bronchospasm, dyspnoea, respiratory depression, abdominal pain, dyspepsia, pancreatitis acute (in patients with a history of cholecystectomy), liver injury, angioedema, dermatitis, fixed eruption, pruritus, urticaria, dysuria, nephropathy toxic, transaminases increased, high anion gap metabolic acidosis.
Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 24: £8.71
Legal category: P
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
PL number: 15513/0104
Date of preparation: 27 Feb 2025