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:

Consult Summary of Product Characteristics (SmPC) for full product details

Presentation:

Migraleve Pink: Tablet containing Buclizine Hydrochloride 6.25mg, Paracetamol 500mg, Codeine Phosphate 8mg. *Migraleve Yellow:* Tablet containing 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 8 tablets (2 Migraleve Pink and 6 Migraleve Yellow) in 24 hours. *Children 12- 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 4 tablets (1 Migraleve Pink and 3 Migraleve Yellow) in 24 hours. *Children under 12 years:* Do not use.

Contraindications:

Paediatric patients undergoing tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome, in women during breastfeeding, in patients known to be CYP2D6 ultra-rapid metabolisers, in patients with head injury, in conditions in which intracranial pressure is increased, in patients at risk of paralytic ileus and in patients with acute respiratory depression, obstructive bowel disorders, hypersensitivity to ingredients, or children below 12 years of age.

Precautions:

Migraine must be medically diagnosed. Should not be taken continuously for extended periods, or for longer than 3 days without the advice of a doctor. Cautions in children with compromised respiratory function. Codeine: Codeine is an opioid agent and therefore prolonged use or 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

depressants (CNS), monoamine oxidase inhibitors (MAOIs). Use for longer than 3 days can make headaches worse. 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. Buclizine: Buclizine is a sedating antihistamine which may enhance sedative effects of central nervous system depressants. It has an antimuscarinic action and therefore it should be used with caution in prostatic hypertrophy, urinary retention, also where susceptibility exists to angle-closure glaucoma.

Interactions:

Codeine: 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 monoamine oxidase inhibitors (MAOIs) or who have used MAOIs in the previous two weeks. Paracetamol: Drugs inducing hepatic microsomal enzymes. Paracetamol may interact with drugs inducing hepatic microsomal enzymes. Speed of absorption is possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, and metoclopramide or domperidone, whilst possible reduction in absorption by cholestyramine. Prolonged paracetamol 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, whilst chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose.Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. Buclizine: Buclizine has an additive sedative effect with alcohol and other CNS depressants and has an additive antimuscarinic action with other antimuscarinic drugs such atropine and some antidepressants (both tricyclics and MAOIs).

Fertility, Pregnancy and lactation:

Not to be used in pregnancy unless benefits to the mother outweigh risk to fetus. Codeine is not recommended in breastfeeding women. Please consult the SmPC for full details.

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.

Side effects:

Prolonged use can cause codeine addiction and worsen headaches.

Very common: Headache, somnolence, flushing, nausea.

Common: Hyperhidrosis, vomiting, constipation, dry mouth, dizziness.

Uncommon: Rash, euphoric mood, drug withdrawal syndrome.

Very rarely: Hypersensitivity and anaphylactic reaction.

Not known: Blood disorder (including thrombocytopenia and agranulocytosis), drug dependence, psychomotor skills impairment, blurred vision, bronchospasm, dyspnoea, increased viscosity of bronchial secretion, 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 and respiratory depression. For other known ADRs associated with codeine use and codeine class effects please consult the SmPC.

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: 08 June 2022

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:

Consult Summary of Product Characteristics (SmPC) for full product details

Presentation:

Tablet containing 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 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 8 tablets (2 Migraleve Pink and 6 Migraleve Yellow) in 24 hours. *Children 12-15 years:* 1 Migraleve Pink initially, followed by 1 Migraleve Yellow every 4 hours if symptoms persist. Maximum 4 tablets (1 Migraleve Pink and 3 Migraleve Yellow) in 24 hours. *Children under 12 years:* Do not use.

Contraindications:

Paediatric patients undergoing tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome, in women during breastfeeding, in patients known to be CYP2D6 ultra-rapid metabolisers, in patients with head injury, in conditions in which intracranial pressure is increased, in patients at risk of paralytic ileus and in patients with acute respiratory depression, obstructive bowel disorders, hypersensitivity to ingredients, or children below 12 years of age.

Precautions:

Migraine must be medically diagnosed. Should not be taken continuously for extended periods, or for longer than 3 days without the advice of a doctor. Cautions in children with compromised respiratory function. Codeine: Codeine is an opioid agent and therefore prolonged use or 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 depressants (CNS), monoamine oxidase inhibitors (MAOIs). Use for longer than 3 days can make headaches worse. 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.Buclizine: Buclizine is a sedating antihistamine which may enhance

sedative effects of central nervous system depressants. It has an antimuscarinic action and therefore it should be used with caution in prostatic hypertrophy, urinary retention, also where susceptibility exists to angle-closure glaucoma.

Interactions:

Codeine: 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 monoamine oxidase inhibitors (MAOIs) or who have used MAOIs in the previous two weeks. Paracetamol: Drugs inducing hepatic microsomal enzymes. Speed of absorption is possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, and metoclopramide or domperidone, whilst possible reduction in absorption by cholestyramine. Prolonged paracetamol 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, whilst chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. Buclizine: Buclizine has an additive sedative effect with alcohol and other CNS depressants and has an additive antimuscarinic action with other antimuscarinic drugs such atropine and some antidepressants (both tricyclics and MAOIs).

Fertility, Pregnancy and lactation:

Not to be used in pregnancy unless benefits to the mother outweigh risk to fetus. Codeine is not recommended in breastfeeding women. Please consult the SmPC for full details.

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.

Side effects:

Prolonged use can cause codeine addiction and worsen headaches.

Very common: Headache, somnolence, flushing, nausea.

Common: Hyperhidrosis, vomiting, constipation, dry mouth, dizziness.

Uncommon: Rash, euphoric mood, drug withdrawal syndrome.

Very rarely: Hypersensitivity and anaphylactic reaction.

Not known: Blood disorder (including thrombocytopenia and agranulocytosis), drug dependence, psychomotor skills impairment, blurred vision, bronchospasm, dyspnoea, increased viscosity of bronchial secretion, 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 and respiratory depression. For other known ADRs associated with codeine use and codeine class effects please consult the SmPC.

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: 08 June 2022

Long-form EI (for more information, see rule 41 of the PAGB professional code)

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

Consult Summary of Product Characteristics (SmPC) for full product details

Presentation:

Tablet containing 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:

A*dults 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 8 tablets (2 Migraleve Pink and 6 Migraleve Yellow) in 24 hours. *Children 12-15 years:* 1 Migraleve Pink initially, followed by 1 Migraleve Yellow every 4 hours if symptoms persist. Maximum 4 tablets (1 Migraleve Pink and 3 Migraleve Yellow) in 24 hours. *Children under 12 years:* Do not use.

Contraindications:

Paediatric patients undergoing tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome, in women during breastfeeding, in patients known to be CYP2D6 ultra-rapid metabolisers, in patients with head injury, in conditions in which intracranial pressure is increased, in patients at risk of paralytic ileus and in patients with acute respiratory depression, obstructive bowel disorders, hypersensitivity to ingredients, or children below 12 years of age.

Precautions:

Migraine must be medically diagnosed. Should not be taken continuously for extended periods, or for longer than 3 days without the advice of a doctor. Cautions in children with compromised respiratory function. Codeine: Codeine is an opioid agent and therefore prolonged use or 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 depressants (CNS), monoamine oxidase inhibitors (MAOIs). Use for longer than 3 days can make headaches worse. 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.

Interactions:

Codeine: 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 monoamine oxidase inhibitors (MAOIs) or who have used MAOIs in the previous two weeks. Paracetamol: Drugs inducing hepatic microsomal enzymes. Speed of absorption is possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, and metoclopramide or domperidone, whilst possible reduction in absorption by cholestyramine. Prolonged paracetamol 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, whilst chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose.Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors.

Fertility, Pregnancy and lactation:

Not to be used in pregnancy unless benefits to the mother outweigh risk to fetus. Codeine is not recommended in breastfeeding women. Please consult the SmPC for full details.

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.

Side effects:

Prolonged use can cause codeine addiction and worsen headaches.

Very common: Headache, somnolence, flushing, nausea.

Common: Hyperhidrosis, vomiting, constipation, dry mouth, dizziness.

Uncommon: Rash, euphoric mood, drug withdrawal syndrome.

Very rarely: Hypersensitivity and anaphylactic reaction.

Not known: Blood disorder (including thrombocytopenia and agranulocytosis), drug dependence, bronchospasm, dyspnoea, 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 and respiratory depression. For other known ADRs associated with codeine use and codeine class effects please consult the SmPC.

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: 08 June 2022