INTERNATIONAL ABBREVIATED PRESCRIBING INFORMATION: MOVICOL®-Half, MOVICOL® Paediatric Chocolate and MOVICOL® Paediatric Plain (macrogol 3350 + sodium chloride + sodium hydrogen carbonate + potassium chloride)

Presentation: 6.9g sachet containing powder for oral solution. Each sachet contains: macrogol 3350 6.563g; sodium chloride 0.1754g; sodium hydrogen carbonate 0.0893g; potassium chloride 0.0233g (MOVICOL®-Half) or 0.0251g (MOVICOL® Paediatric Plain) or 0.0159g (MOVICOL® Paediatric Chocolate). Excipients: MOVICOL® Paediatric Chocolate contains benzyl alcohol 7.0mg per sachet.

Indications: Indications and prescribing status may vary according to country. For the treatment of chronic constipation with MOVICOL® Paediatric Plain in children 1-11 years of age and with MOVICOL® Paediatric Chocolate 2-11 years of age. For the treatment of faecal impaction (defined as refractory constipation with faecal loading of the rectum and/or colon) and for the prevention of recurrence of faecal impaction, with MOVICOL® Paediatric Chocolate and MOVICOL® Paediatric Plain in children 5-11 years of age. For the treatment of chronic constipation and faecal impaction with MOVICOL®-Half in 12 years and above. (Please consult your local prescribing information.)

Posology and administration: Dosing varies according to indication and age, or if impaired cardiovascular function or renal insufficiency is present. Constipation in children using MOVICOL® Paediatric Plain: 1 sachet daily for 1-6 years and 2 sachets daily for 7-11 years. For children below 2 years of age, the maximum recommended dose should not exceed 2 sachets a day. Constipation in children using MOVICOL® Paediatric Chocolate: 1 sachet daily for 2-6 years and 2 sachets daily for 7-11 years. Dose should be adjusted up or down as required to produce regular soft stools, maximum dose needed does not normally exceed 4 sachets a day. Faecal impaction in children aged 5 to 11 years using MOVICOL® Paediatric Plain or MOVICOL® Paediatric Chocolate: 4-12 sachets daily in divided doses, all consumed within a 12-hour period, course of treatment is for up to 7 days. Constipation treatment using MOVICOL® Half in 12 years and above: 2-6 sachets daily. Faecal impaction treatment using MOVICOL® Half in 12 years and above: 16 sachets daily and does not normally exceed a course of three days. Country approved prescribing information should be consulted. Each sachet should be dissolved in 62.5ml of water.

Contraindications: Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease and ulcerative colitis, toxic megacolon, hypersensitivity to the active substances or to any of the ingredients.

Warnings and precautions: Adequate fluid intake must be maintained. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure), MOVICOL® should be stopped immediately, electrolytes measured, and any abnormality treated appropriately. This medicinal product should be administered with caution to patients with impaired gag reflex, reflux oesophagitis or diminished levels of consciousness. MOVICOL® Paediatric Chocolate contains benzyl alcohol 7.0mg per sachet. Benzyl alcohol may cause anaphylactoid reactions. If used for more than a week in children less than 3 years old, medical advice should be provided due to increased risk of accumulation of benzyl alcohol. MOVICOL® Paediatric and MOVICOL® Half contain 93.4mg (4.062mmol) sodium per sachet, to be considered for those on a low salt diet.

Interactions: There is a possibility that the absorption of other medicinal products could be transiently reduced during use with MOVICOL®. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

Fertility, pregnancy and lactation: No data on the effects of MOVICOL® on the fertility of humans or use in pregnancy and breast feeding. Systemic exposure to macrogol 3350 is negligible. MOVICOL® can be used during pregnancy and breast-feeding.

Undesirable effects: Reactions related to the gastrointestinal tract occur most commonly. These may include: abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal discomfort. Allergic reactions, including anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria. Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia. Erythema. Headache. Peripheral oedema. Prescribers should consult country approved prescribing information for further information in relation to undesirable effects.

Overdose: Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances. Severe abdominal pain or distension can be treated by nasogastric aspiration.

Price and pack sizes: Price and pack sizes vary according to country.

Legal category: Prescribing status may vary according to country.

ATC code: A06A D65

Marketing authorisation holder: Norgine BV, Antonio Vivaldistraat 150, 1083HP Amsterdam, The Netherlands.
Product licence number: Product licence numbers vary according to country.
Date International Abbreviated Prescribing Information prepared: August 2020
Company reference: GL-GE-MOV-2000005
MOVICOL®-Half, MOVICOL® Paediatric Chocolate and MOVICOL® Paediatric Plain have varying availabilities and licensing internationally. Before prescribing, consult your country approved prescribing information, available from your local distributor or Norgine Limited.

Adverse events should be reported to your regulatory agency. Adverse events should also be reported to your local distributor or Norgine Limited, Norgine House, Moorhall Road, Harefield, Uxbridge, Middlesex UB9 6NS, United Kingdom.
Email: globalmedinfo@norgine.com
This may vary according to country regulations.

INTERNATIONAL ABBREVIATED PRESCRIBING INFORMATION: MOVICOL® Ready to Take (macrogol 3350 + sodium chloride + sodium hydrogen carbonate + potassium chloride)

Presentation: Clear, colourless to light yellow, oral solution in a 25ml sachet. Each sachet contains: macrogol 3350 13.125g; sodium chloride 350.8mg; sodium hydrogen carbonate 178.6mg; potassium chloride 50.2mg.

Indication: A laxative for the treatment of constipation and faecal impaction in adolescents and adults. Not recommended for children below 12 years.

Dosage and administration: Prescribing status may vary according to country. Can be taken directly from sachet. No need to dilute with water. Can be taken at any time with or without food or drink. Not to be used if pack is damaged. Patients should drink sufficient amounts of fluids (generally 2.0-2.5 litres per day) to maintain good health. *Constipation* – one sachet 1-3 times daily, according to patient response. Treatment usually lasts for about 2 weeks. Extended use may be necessary if constipation is caused by an illness (e.g. Parkinson's disease or multiple sclerosis), or if the patient is on medicines that cause constipation. *Faecal impaction* – eight sachets a day all within a 6 hour period. Patients with faecal impaction are recommended to drink an extra 1 litre of fluid per day. Treatment can be for up to 3 days. No dose adjustments required for patients with renal insufficiency.

Contraindications: Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract such as ulcerative colitis, Crohn's disease or toxic megacolon; hypersensitivity to any of the ingredients.

Warnings and precautions: Adequate fluid intake must be maintained. Diagnosis of faecal impaction should be confirmed by physical or radiological examination. If patient develops any symptoms indicating a shift in fluids / electrolytes MOVICOL® Ready to Take should be stopped immediately, electrolytes should be measured and any abnormality should be treated appropriately. *Heart conditions* – patients with a heart condition should not take more than 2 sachets in any one hour. Contains 186.87 mg (8.125 mmol) sodium per dose. To be considered for those on a low salt diet.

Interactions: Macrogol raises the solubility of medicinal products which are soluble in alcohol and relatively insoluble in water. The absorption of other medicinal products could be transiently reduced. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

Fertility, pregnancy and lactation: No data on the effects of MOVICOL® on fertility in humans. Can be taken during pregnancy and whilst breastfeeding. Limited data from the use of MOVICOL® in pregnant women. No effects on pregnancy and lactation are anticipated as systemic exposure is negligible.

Undesirable effects: Reactions related to the gastrointestinal tract occur most commonly. The frequency of the adverse events for MOVICOL® Ready to Take is unknown. Possible side effects include: allergic reactions, including anaphylactic reactions, dyspnoea, allergic skin reactions (angioedema, urticaria, pruritus, rash, erythema), electrolyte disturbances (particularly hyperkalaemia and hypokalaemia), headache, abdominal pain, diarrhoea (mild diarrhoea usually responds to dose reduction), vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anorectal discomfort, peripheral oedema.

Overdose: Severe abdominal pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Price and pack sizes: Price and pack sizes vary according to country.

Legal category: Prescribing status may vary according to country.

ATC code: A06A D65

Marketing authorisation holder: Norgine BV, Antonio Vivaldistraat 150, 1083HP Amsterdam, The Netherlands.

Product licence number: Product licence numbers vary according to country.

Date of preparation: May 2020

Company reference: GL-GE-MOV-2000002

MOVICOL® Ready to Take has varying availability and licensing internationally. Before prescribing, consult your country approved prescribing information, available from your local distributor or Norgine Limited.

Adverse events should be reported to your regulatory agency. Adverse events should also be reported to your local distributor or Norgine Limited, Norgine House, Moorhall Road, Harefield, Uxbridge, Middlesex, UB9 6NS, United Kingdom. Email: globalmedinfo@norgine.com

INTERNATIONAL ABBREVIATED PRESCRIBING INFORMATION: MOVICOL® (macrogol 3350 + sodium chloride + sodium hydrogen carbonate + potassium chloride)

Presentation: 13.8g sachet containing powder for oral solution. Each sachet contains: macrogol 3350 13.125g, sodium chloride 0.3507g, sodium bicarbonate 0.1785g, potassium chloride 0.0466g.

Indications: Treatment of constipation and faecal impaction (defined as refractory constipation with faecal loading of the rectum and/or colon). Indications may vary according to country.

Posology and method of administration: Prescribing status may vary between countries. Adults, adolescents and older people: Constipation: 1 – 3 sachets daily in divided doses according to individual response. Faecal impaction: 8 sachets daily. A course of treatment for faecal impaction does not normally exceed 3 days. Children below 12 years old: not recommended.

Contraindications: Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis, and toxic megacolon. Hypersensitivity to the active substances or to any of the ingredients.

Warnings and precautions: The fluid content of MOVICOL® when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL® should be stopped immediately, electrolytes measured, and any abnormality treated appropriately. Patients with a heart condition should not take more than 2 sachets in any one hour. No dose adjustments required for patients with renal insufficiency. Contains 186.87mg (8.125mmol) sodium per dose. To be considered for those on a low salt diet.

Interactions: Absorption of other medicinal products could be transiently reduced during use of MOVICOL®. There have been some isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

Fertility, pregnancy and lactation: No data on the effects of MOVICOL® on the fertility of humans are available. Limited data on exposed pregnancies are available. No clinical effects during pregnancy or on the breastfed newborn/infant are anticipated since systemic exposure to macrogol 3350 is negligible. Can be used during pregnancy and breast-feeding.

Undesirable effects: Reactions related to the gastrointestinal tract occur most commonly. These may include: abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal discomfort. Allergic reactions, including anaphylaxis, angioedema, dyspnoea, pruritus, rash, erythema and urticaria. Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia. Headache. Peripheral oedema. Prescribers should consult country approved prescribing information for further information in relation to undesirable effects.

Overdose: Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances. Severe abdominal pain or distension can be treated by nasogastric aspiration.

Price and pack sizes: Price and pack sizes vary according to country.

Legal category: Prescribing status may vary according to country.

ATC code: A06A D65

Marketing authorisation holder: Norgine BV, Antonio Vivaldistraat 150, 1083HP Amsterdam, The Netherlands.

Product licence number: Product licence numbers vary according to country.

Date prepared: July 2020

Company reference: GL-GE-MOV-2000003

MOVICOL® has varying availability and licensing internationally. Before prescribing, consult your country approved prescribing information, available from your local distributor or Norgine Ltd.

Adverse events should be reported to your regulatory agency. Adverse events should also be reported to your local distributor or Norgine Limited, Norgine House, Moorhall Road, Harefield, Uxbridge, Middlesex UB9 6NS, United Kingdom.
Email: globalmedinfo@norgine.com

INTERNATIONAL ABBREVIATED PRESCRIBING INFORMATION: MOVICOL® Liquid (macrogol 3350 + sodium chloride + sodium hydrogen carbonate + potassium chloride) Presentation: Concentrate for oral solution. Each 25ml contains: macrogol 3350 13.125g, sodium chloride 0.3507g, sodium hydrogen carbonate 0.1785g, potassium chloride 0.0466g.
Indication: For the treatment of chronic constipation. Indications may vary according to country.
Posology and administration: Adults, adolescents and the elderly: 25ml diluted in 100ml of water 1-3 times daily in divided doses, according to individual response. Children below 12 years old: not recommended.
Contraindications: Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis, and toxic megacolon. Hypersensitivity to the active substances or to any of the excipients.
Warnings and precautions: Adequate fluid intake must be maintained. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure), MOVICOL® Liquid should be stopped immediately, electrolytes measured, and any abnormality treated appropriately. No dose adjustments required for patients with renal insufficiency. Contains 45.6mg of benzyl alcohol in each 25ml dose which is equivalent to 1.825mg/ml. Benzyl alcohol may cause anaphylactoid reactions. Contains ethyl (E214) and methyl (E218) parahydroxybenzoates which may cause allergic reactions. Contains 186.87mg (8.125mmol) sodium per dose, to be considered for those on a low salt diet.
Interactions: Absorption of other medicinal products could be transiently reduced during use with MOVICOL® Liquid. There have been some isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.
Fertility, pregnancy and lactation: No data on the effects of MOVICOL® on the fertility of humans. Limited clinical data on exposed pregnancies are available. No clinical effects during pregnancy or on the breastfed newborn/infant are anticipated, since systemic exposure to macrogol 3350 is negligible. MOVICOL® can be used during pregnancy and breast-feeding.
Undesirable effects: Reactions related to the gastrointestinal tract occur most commonly. These may include: abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal discomfort. Allergic reactions, including anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria. Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia. Erythema. Headache. Peripheral oedema. Prescribers should consult country approved prescribing information for further information in relation to undesirable effects.
Overdose: Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances. Severe abdominal pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.
Price and pack sizes: Price and pack sizes may vary according to country.
Legal category: Prescribing status may vary according to country.
ATC code: A06A D65
Marketing authorisation holder: Norgine BV, Antonio Vivaldistraat 150, 1083HP Amsterdam, The Netherlands.
Product licence number: Product licence numbers vary according to country.
Date prepared: July 2020
Company reference: GL-GE-MOV-2000004
MOVICOL® Liquid has varying availability and licensing internationally. Before prescribing, consult your country approved prescribing information, available from your local distributor or Norgine Ltd.

Adverse events should be reported to your regulatory agency. Adverse events should also be reported to your local distributor or Norgine Limited, Norgine House, Moorhall Road, Harefield, Uxbridge, Middlesex UB9 6NS, United Kingdom.
Email: globalmedinfo@norgine.com