### 1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

**SCHEDULING STATUS**

**S0**

**PROPRIETARY NAME AND DOSAGE FORM**

**MOVICOL CHOCOLATE** (powder for reconstitution)

**COMPOSITION**

Each 13,9 g sachet of MOVICOL CHOCOLATE contains:

| | |
|---|---|
| Macrogol (PEG) 3350 | 13,125 g |
| Sodium Chloride | 350,7 mg |
| Sodium Bicarbonate | 178,5 mg |
| Potassium Chloride | 31,7 mg |

The content of electrolyte ions per sachet when diluted to 125 ml of solution is as follows:

| | |
|---|---|
| Sodium | 65 mmol/l |
| Chloride | 51 mmol/l |
| Potassium | 5,4 mmol/l |
| Bicarbonate | 17 mmol/l |

*Excipients:*

Acesulfame potassium, chocolate flavour (containing maltodextrin, acacia gum, vegetable oils and fats, propylene glycol, ethyl alcohol)

Contains sweetener: Acesulfame potassium 0,05 g

Sugar free

**CATEGORY AND CLASS**

A 11.5 Medicines acting on the gastrointestinal tract. Laxatives

**PHARMACOLOGICAL ACTION**

**Pharmacodynamic properties**

MOVICOL CHOCOLATE, an iso-osmotic laxative, is a combination of Macrogol 3350 (polyethylene glycol) and electrolytes.

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

**Pharmacokinetic properties**

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

The laxative action of macrogol has a time course which will vary according to the severity of the constipation being treated.

**INDICATIONS**

For the treatment of chronic constipation.

**CONTRAINDICATIONS**

- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, gastric retention, peptic ulceration and severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon.
- Hypersensitivity to the active ingredients or to any of the excipients.
- Not recommended for children under 12 years of age.

**WARNINGS AND SPECIAL PRECAUTIONS**

MOVICOL CHOCOLATE should not be used in the presence of abdominal pain, nausea or vomiting.

MOVICOL CHOCOLATE should not be used continuously unless directed by a doctor. Frequent or prolonged use of laxatives may result in dependence and loss of normal bowel function.

If patients develop any symptoms indicating shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL CHOCOLATE should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

If there is a sudden change in bowel habits that has persisted for a period greater than two weeks, a medical practitioner should be consulted.

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. MOVICOL CHOCOLATE should be discontinued and medical advice obtained.

## INTERACTIONS

No clinical interactions with other medicinal products have been reported. Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.

There is therefore a theoretical possibility that the absorption of such medicinal products could be transiently reduced.

## HUMAN REPRODUCTION

Safety in pregnancy has not been established.

## DOSAGE AND DIRECTIONS FOR USE

**Adults:** 1 to 3 sachets daily in divided doses, according to individual response, each sachet reconstituted in 125 ml water and taken orally.

**Elderly:** Initially, one sachet daily is recommended.

No dosage change is needed to be made for patients with renal insufficiency.

A course of treatment with MOVICOL CHOCOLATE does not normally exceed two weeks, although this can be repeated if required.

Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's disease, or induced by regular constipating medication, in particular opioids and antimuscarinics.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily, in divided doses, each reconstituted with 125 ml water and taken orally.

## SIDE EFFECTS

Abdominal distension, pain, borborygmi, nausea, abdominal cramps, mild diarrhoea which usually reponds to dose reduction, vomiting and anal irritation may occur.

Urticaria and allergic reactions, including anaphylaxis to macrogol (polyethylene glycol) have been reported.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

### Symptoms

Severe pain or distension, diarrhoea or vomiting is associated with overdosage.

### Treatment

Severe pain or distension, associated with overdosage, can be treated by nasogastric aspiration.

In the case of gross accidental overdosage, extensive fluid loss by diarrhoea or vomiting may require correction with generous amounts of fluid and electrolytes.

## IDENTIFICATION

White to light brown free flowing powder with a chocolate flavour and odour. The reconstituted solution is slightly hazy.

## PRESENTATION

The powdered product is packed in 4-layer laminated sachets with label printing on both sides of the sachet. The laminate consists of paper, low density polyethylene, and aluminium foil. The sachets are sealed in pairs with a perforation line which allows for separation of the 2 sachets and are marked with the batch number and expiry date.
20 or 30 sachets are packed into an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

## STORAGE INSTRUCTIONS

Sachet: Store at or below 25 °C.

Reconstituted solution: Store at 2 °C to 8 °C (in a refrigerator and keep covered). Discard any solution not used within 24 hours.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

## REGISTRATION NUMBER

45/11.5/0681

## NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE**

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