Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mil-Par Oral Suspension
Magnesium Hydroxide 300mg/5ml
Liquid Paraffin 1.25ml/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml spoonful contains 300 mg of magnesium hydroxide and 1.25 ml liquid paraffin.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
Smooth, white, opaque, non-gritty viscous suspension with a characteristic bland taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

MIL-PAR is recommended for the temporary relief of occasional constipation.

4.2 Posology and method of administration

Adults (including the elderly):	One or two tablespoonsful (15 to 30 ml). Before breakfast or at bedtime.
Children aged 7 years and over:	Half to one tablespoonful (7.5 to 15 ml) at bedtime.
Children aged 2 to 7 years:	One or two teaspoonful (5 to 10 ml) at bedtime.

Not recommended for children under two years of age.

MIL-PAR should not be given to children except on medical advice.

MIL-PAR is for oral administration only. If desired, the dose may be mixed with half a glass of milk or water.

4.3 Contraindications

Use is contraindicated in children under two years of age.

Mil-par is contraindicated in those who have hypersensitivity to the active components (section 2) or the any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Care is required in patients with swallowing difficulties.
- This product should not be given to patients with symptoms of appendicitis, intestinal obstruction, inflammatory bowel disease or abdominal pain of unknown origin.
- Magnesium salts may cause central nervous system depression in the presence of renal insufficiency

- If laxatives are needed every day, if there is persistent abdominal pain, or if symptoms persist, consult your doctor.
- If you are taking medication, suffer from kidney disease or are under a doctor`s care, then you should consult your doctor before taking this.
- Prolonged continuous use is not recommended.
- May be harmful for people on a low sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Interference with the absorption of fat soluble vitamins may occur with liquid paraffin. However, there is no evidence that this occurs with MIL-PAR and due to the low content of liquid paraffin in the product, it is unlikely.

4.6 Fertility, pregnancy and lactation

MIL-PAR has been widely used during pregnancy without ill-effect, but as with all medicines during pregnancy and lactation, advice from the doctor should be sought.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following side effects have been reported with liquid paraffin:

- Anal seepage of paraffin and consequent anal irritation after prolonged use.
- Granulomatous reactions caused by absorption of small quantities of liquid paraffin.
- Lipoid pneumonia (by accidental inhalation) may occur and caution is, therefore, required in patients with swallowing difficulties.

These side effects have not been reported with MIL-PAR and are unlikely to occur due to the low content of liquid paraffin in the product.

4.9 Overdose

If large quantities are ingested withdraw medication, supportive treatment may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Magnesium hydroxide has an indirect cathartic action, which results from water retention in the stomach lumen due to increased osmotic pressure.

Liquid paraffin acts as a mild laxative by softening stools thus easing defecation.

5.2 Pharmacokinetic properties

MIL-PAR exerts its therapeutic effect within the gastrointestinal tract and does not, therefore, depend upon pharmacokinetic properties.

5.3 Preclinical safety data

There are no preclinical data of relevance which are additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.
Use within 28 days of opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

100, 200 and 500 ml blue PVC bottles sealed with white polypropylene LDPE snap-on hinged closures with removable, tamper-proof tear strips (jaycap closures).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 417/14/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 22 December 2007

10 DATE OF REVISION OF THE TEXT

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