Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

RAZALAX ADULT RAZALAX CHILDREN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Razalax adult
Each single-dose container contains:
Active ingredient: Glycerol 6.75 g

Razalax children
Each single-dose container contains:
Active ingredient: Glycerol 2.25 g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Rectal solution
Yellow to brown, dense liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Constipation

4.2 Posology and method of administration

Posology

Adults: 1 or 2 single-dose adult containers in 24 hours.
Even in the event of severe constipation, do not introduce more than 2 doses into the rectum at any one time.

Children: 1 or 2 single-dose child containers in 24 hours.
Even in the event of severe constipation, do not introduce more than 2 doses into the rectum at any one time.

4.3 Contraindications

RAZALAX ADULT and RAZALAX CHILDREN are contraindicated in the following cases:
- hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- anal-rectal disorders
- haemorrhagic rectocolitis
- haemorrhoid inflammation.

4.4 Special warnings and precautions for use

Continuous use of laxatives can be habit-forming and can cause other problems.
Laxatives should be avoided in patients experiencing:
• Persistent unexplained change in bowel habits
• Palpable mass in the abdomen or the pelvis

• Persistent rectal bleeding without anal symptoms
• Narrowing of stool caliber
• Unexplained weight loss, iron deficiency anaemia, fever, or nocturnal symptoms
Family history of colon cancer, or inflammatory bowel disease.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions with other drugs have been observed.

4.6 Fertility, pregnancy and lactation

Given its chemical-physical properties, rectally-administered glycerine can be useful during pregnancy or after giving birth.

4.7 Effects on the ability to drive and use machines

Razalax has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The only effects that may be seen are irritation to the rectal area. These are usually mild and do not require medical intervention.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il.

4.9 Overdose

There are no known symptoms of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: laxatives.

ATC code: A06AG04

Glycerine aids evacuation by locally stimulating the rectal mucous, through contact, without involving the distal portions of the intestine.
The muscle contraction causes the expulsion of faeces within a short space of time and, at the same time, eliminates all residue of the stimulant liquid.
Thanks to its hygroscopic and osmotic properties, glycerine also recalls water to the intestinal lumen, which softens the faeces and stimulates rectal muscle contraction. Glycerine also lubricates faeces.
The microclism also includes wheat starch, which has an emollient, protective action on mucous; the extract of malva and camomile help improve local tolerability.

5.2 Pharmacokinetic properties

Glycerine-based preparations for rectal use act as laxatives without the drug being absorbed by the intestinal mucous. When present in the intestinal lumen, glycerine is in fact able to perform its therapeutic action not as a consequence of its systemic absorption, but simply on the basis of a physical mechanism.
Orally-administered glycerine is readily absorbed by the intestine and metabolised with carbon monoxide and glycogen or used in the synthesis of fats.

5.3 Preclinical safety data

The literature has no reports of toxic effects following the use of glycerine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mauve fluid extract, chamomile fluid extract, wheat starch, purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and contents of container

RAZALAX ADULT Squeezable bottles with cannula and cap in low density polyethylene, available in box containing 6 single-dose containers, each of 9 g.

RAZALAX CHILDREN Squeezable bottles with cannula and cap in low density polyethylene, available in box containing 6 single-dose containers, each of 3 g.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION NUMBERS

RAZALAX ADULT 158-37-34394-00
RAZALAX CHILDREN: 158-38-34408-00

8. MARKETING AUTHORIZATION HOLDER & IMPORTER

RAZ PHARMACEUTICS LTD., 31 Gesher haetz Street, Emek Hefer Industrial Park, Israel

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