Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celevac 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of methylcellulose.

Excipients with known effect:
Lactose monohydrate (110.467 per tablet)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Circular, biconvex, pink tablets embossed 'CELEVAC' on one face with a breakline on the other face.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Celevac Tablets are indicated in adults and children over 6 years of age for the treatment of constipation and in patients requiring a high fibre diet.

4.2 Posology and method of administration

Posology

Use should be under medical supervision. It is recommended that the tablets should be broken in the mouth before swallowing. Celevac Tablets swell in contact with water and should therefore be swallowed carefully.

It is not recommended that these tablets be taken before going to bed.

Adults
The usual dose is 3-6 tablets twice daily, usually with 300 ml of liquid.

Paediatric population
Children over 12 years of age
The usual dose is 3-6 tablets twice daily, usually with 300 ml of liquid.

Children 6 to 12 years of age
Half the adult dose.

Dosage of tablets and liquid should be adjusted within the above recommendations according to individual requirements.

Route of administration
Oral

4.3 Contraindications

Celevac Tablets are contraindicated in patients:

- hypersensitive to methylcellulose or to any of the excipients listed in section 6.1;
- with imminent or threatened intestinal obstruction;
- with faecal impaction;
- who have difficulty in swallowing;
- with colonic atony;
- with infective bowel disease;
- with severe dehydration.

4.4 Special warnings and precautions for use

Guidance on fluid intake is stated in section 4.2.
Adequate fluid intake should be maintained to avoid intestinal obstruction.
Methylcellulose should be taken with sufficient fluid to prevent faecal impaction or oesophageal obstruction.

Bowel obstruction is a rare complication of treatment with any bulk-forming hydrophilic colloid (see section 4.8).

Supervision may be necessary for patients who:
- are elderly;
- are debilitated;
- have intestinal narrowing;
- have decreased intestinal motility.

Constipation can be a symptom of serious underlying disease, e.g. cancer. If laxatives are needed every day, the cause of constipation should be investigated.

Celevac Tablets contain lactose
Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency of glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Bulk laxatives such as oral methylcellulose lower the transit time through the gut and could affect the absorption of other drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy
Celevac Tablets should not be used during pregnancy except under medical supervision.

4.7 Effects on ability to drive and use machines

Celevac Tablets have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most commonly reported reactions with methylcellulose are of a gastrointestinal nature and include flatulence and abdominal distension.

Reactions not already stated, which are attributable to bulk-forming laxatives include gastrointestinal obstruction, faecal impaction and hypersensitivity.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms
Methylcellulose is not absorbed. The features to be expected would be abdominal distension which may be followed by intestinal obstruction.

Management
Gastric lavage should be employed where appropriate. The patient should be observed and fluid given. If obstruction develops, appropriate measures such as rectal washout must be taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Bulk-forming laxative
ATC code: A06AC06

The active ingredient is a simple bulking agent.

Methylcellulose is a hydrophilic colloid which absorbs water causing it to swell to a soft gel of uniform consistency.

5.2 Pharmacokinetic properties

The active ingredient is not absorbed from the gut.

5.3 Preclinical safety data

None listed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Saccharin sodium
Povidone
Erythrosine (E127)
Strawberry flavour 52.318 AP
Talc
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene securitainers, containing 112 or 250 tablets with polyethylene cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Amdipharm Limited
Temple Chambers
3 Burlington Road
Dublin 4
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1142/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 January 1988

Date of last renewal: 8 March 2008

10 DATE OF REVISION OF THE TEXT

July 2015