Summary of product characteristics for Bekunis Dragees

1. Designation of the pharmaceutical product

Bekunis Dragees
Active ingredient: Dry extract of Tinnevelly senna pods

2. Qualitative and quantitative composition

1 enteric-coated tablet contains : 150-220 mg dry extract from Tinnevelly senna pods, corresponding to 20 mg of hydroxyanthracene glycosides, calculated as sennoside B, extraction agent: water.

This medicinal product contains sucrose (sugar) and lactose.

For the complete list of the other constituents see section 6.1.

3. Form of administration

Enteric-coated tablets

4. Clinical data

4.1 Therapeutic indications

Laxative

4.2 Dosage instructions, method and duration of administration

The maximum daily intake must not exceed 30 mg of hydroxyanthracene derivatives; this corresponds to 1 coated tablet.
This results in the following dosages:
Adults and adolescents over 12 years of age take 1 coated tablet 1x daily before retiring. The individually correct dose is the smallest one necessary to produce loosely formed stools. The effect sets in after 8-12 hours.

4.3 Contra-indications

Bekunis Senna dragees must not be taken: in cases of allergy to Tinnevelly senna pods or to one of the other constituents of the medicinal product, in cases of ileus, appendicitis, chronic inflammatory intestinal diseases such as for example Crohn's disease, colitis ulcerosa, in cases of abdominal pains of unknown genesis, in cases of severe dehydration with water and salt loss, by children under 12 years of age.
It is drawn to the attention of the patient in the package information sheet that a doctor should be consulted before taking the preparation at the same time as cardiac glycosides, antiarrhythmic drugs, diuretics, cortisone and similar substances to cortisone or liquorice root.

4.4 Special warnings and precautions for safe use

The use of stimulating laxatives for more than a short-term application may lead to increased sluggishness of the bowels. The preparation should only be taken if the constipation cannot be remedied by a change of diet or by preparations that act through swelling substances.
Note: Incontinent adults who take Tablets should avoid lengthy skin contact with the faeces by changing the sanitary towel.

4.5 Interactions with other medicinal products and other interactions

The chronic use/abuse of the preparation could lead to a strengthening of the cardiac glycoside effect due to potassium losses as well as to an influence on the effect of antiarrhythmic drugs. Potassium losses may be amplified through a combination of the preparation with diuretics, adrenal cortical steroids or liquorice root.

4.6 Pregnancy and lactation

Bekunis Senna Dragees should only be taken during the first three months of pregnancy if the constipation cannot be remedied by a change of diet or by preparations that act through swelling substances.
Note: Degradation products of the senna pods with a laxative effect such as rhein find their way into the mother's milk in small quantities. No laxative effect has been observed in constipated infants.

4.7 Effects on the ability to drive or operate machinery

No special precautions are necessary.

4.8 Side Effects

The following frequency rates are taken as the basis for assessing side effects:
Very frequent (>1/10)
Frequent (>1/100 to <1/10)
Occasional (>1/1,000 to <1/100)
Rare (>1/10,000 to <1/1,000)
Very rare (<1/10,000)

Very rarely, spasmodic gastro-intestinal disorders may occur. In such cases, it is necessary to reduce the dose. Very rarely it is possible for hypersensitivity reactions (itching, urticaria, local or generalised exanthemas) to occur. In the course of the treatment, a harmless reddening of the urine may occur. In the case of chronic use/abuse of the preparation this could lead to disturbances of the water balance or the electrolyte metabolism. Diarrhoea may occur and may lead in particular to potassium losses. The loss of potassium may in turn lead to disturbances of the cardiac function and to muscular weakness, especially if cardiac glycosides, diuretics and adrenal cortical steroids are taken at the same time. Chronic use may be accompanied by albuminuria and haematuria. Furthermore, a pigmentation of the intestinal mucosa (pseudomelanosis coil) may occur, which however is harmless and usually recedes after discontinuation of the drug.
The following is drawn to the attention of the patient in the package information sheet:
If side effects occur, it is necessary to reduce the dose or possibly to discontinue the use of the medicinal product.
At the first signs of a hypersensitivity reaction, the pharmaceutical product must no longer be taken. If necessary go and see your doctor so that he can treat the side effects that have occurred.

4.9 Overdose

In the case of an inadvertent or intentional overdose, painful spasms of the intestines and severe diarrhoea may occur, leading to water and salt losses as well as possible severe gastrointestinal complaints.
In the directions for use, the attention of the patients is drawn to the following: If an overdose has been taken, please notify a doctor immediately. He will decide what countermeasures (e.g. an infusion of liquid and salts) may be necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vegetable-based stimulating laxative

ATC-Code: A06AB06

Apart from mucins and flavonoids, senna pods contain compounds that derive from anthracene, namely 1.8 dihydroxyanthracene derivatives. These have a laxative effect. In the case of the sennosides and/or their active metabolite in the large intestine, rhein anthrone, which dominate in terms of quantity, this effect is based predominantly on an influence on colonic motility in the form of an inhibition of the stationary contractions and a stimulation of the propulsive contractions. This results in an accelerated passage through the intestines and, by virtue of the shortened contact time, in a reduction of the absorption of liquid. In addition, water and electrolytes are secreted through a stimulation of the active secretion of chloride. It is necessary to reckon with some 8-12 hours for the anthracene derivatives to take effect.

5.2 Pharmacokinetic properties

No systematic investigations regarding the kinetic properties of drug preparations exist, however it can be assumed that aglucones contained in the drug are already absorbed in the upper small intestine. The β-glycosidic bonded glycosides are prodrugs that are neither split nor absorbed in the upper gastrointestinal tract. They are degraded to rhein anthrone in the large intestine through bacterial enzymes. Rhein anthrone is the laxative metabolite. The systemic availability of rhein anthrone is very low. In animal experiments, <5% are excreted in the urine in the form of the oxidised, partly conjugated products rhein and sennidines. The greater part of the rhein anthrone (>90%) is bonded to the intestinal content in the faeces and excreted in the form of polymer compounds.
Active metabolites, such as rhein, find their way into the mother's milk in small quantities. No laxative effect has been observed in suckling infants. In animal experiments, the placental infiltration of rhein is extremely low.

5.3 Preclinical data with regard to safety

Drug preparations have a higher general toxicity than the pure glycosides, probably by virtue of the aglucone content. In vitro, a senna extract was mutagenic, the highly purified substances sennosides A and B were negative. In-vivo investigations of mutagenicity with a defined extract from senna pods were negative. The investigation looked at preparations with a content of 1.4 - 3.5% anthraquinones (calculated as the sum total of the individually determined compounds), which arithmetically correspond to 0.9 - 2.3% of potential rhein, 0.05 - 0.15% of potential aloe-emodin and 0.001 - 0.006 % of potential emodin. Positive findings exist in some cases for aloe-emodin and emodin. Investigations have been carried out with regard to carcinogenicity with an enriched sennoside fraction containing some 40.8% of anthranoids, of which 35% are total sennosides (calculated as the sum total of the individually determined compounds), corresponding to approx. 25.2 % of arithmetically calculated potential total rhein, 2.3% of potential aloe-emodin and 0.007% of potential emodin. The substance examined contained 142ppm of free aloe-emodin and 9ppm of free emodin. In this study carried out on rats over a period of more than 104 weeks with doses up to 25mglkg body weight, no substance-induced increase was observed in the frequency of tumours.

6. Pharmaceutical information

6.1 List of the other constituents

Sucrose,Talc ,Cellulose microcrystalline, Lactose, anhydrous, Eudragit L 30 D, Calcium carbonate, Silicon dioxide methylated, Titanium dioxide, E171, Gelatine, Magnesium stearate, Gum arabic spray dried, Liquid glucose (dry substance), Macrogol 6000, Polysorbate 80, Stearic palmitic acid, Montan glycol wax, Carboximethylcellulose sodium.

6.2 Incompatibilities

None known.

6.3 Storage stability

3 years

Shelf life after first opening

6 months

6.4 Special precautions for warehousing and storage

Do not store above 30°C.

6.5 Nature and contents of the container

Pack containing 45 enteric-coated tablets

6.6 Special precautions for disposal

No special requirements.
Unused medicinal products or waste material must be disposed of in accordance with the national requirements.

7. Name or company name and address of the pharmaceutical enterprise

roha arzneimittel GmbH
P.O. Box 330340
28333 Bremen
Rockwinkeler Heerstr. 100
28355 Bremen

Marketing Authorization Holder

Dexxon LTD., 1 Dexcel Street, Or Akiva 30600

The format of this leaflet was determined by the ministry of health (MOH) and its content was checked and approved by the MOH in June 2011.