



<b>Brand Name</b> : AGOBIS TABLETS	2021
<b>Generic Name</b> : Bisacodyl Tablets BP 5 mg	
<b>Module 1</b> Administrative Information and Product Information	
<b>1.5</b> Product Information	<b>Confidential</b>

## 1.5 PRODUCT INFORMATION

### 1.5.1 Prescribing information (Summary of products characteristics)

#### SUMMARY PRODUCT CHARACTERISTICS

#### 1. Name of drug product:

AGOBIS TABLETS (Bisacodyl Tablets BP 5 mg)

#### 2. Qualitative and Quantitative Composition:

Each Enteric coated tablet contains: Bisacodyl BP 5 mg

#### 3. Pharmaceutical form:

Tablet

#### 4. Clinical particulars:

##### 4.1 Therapeutic indications

For short-term relief of occasional constipation.

##### 4.2 Posology and method of administration

###### Posology

**Route of administration:** Oral.

Short-term treatment for constipation:

*Adults and children over 12 years:* 1 – 2 tablets (5 – 10 mg) daily.

It is recommended to start with the lowest dose. The dose might be adjusted up to the maximum recommended dose to produce regular stools. The maximum daily dose should not be exceeded.

In the management of constipation, once regularity has been restarted dosage should be reduced and can usually be stopped.

Bisacodyl 5 mg gastro-resistant tablets should not be used in children and adolescents under the age of 12 years .

Method of administration



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They should be swallowed whole with an adequate amount of fluid.

The coated tablets should not be taken together with products which reduce the acidity of the upper gastrointestinal tract, such as milk, antacids or proton pump inhibitors, in order not to prematurely dissolve the enteric coating.

No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

#### 4.3 Contraindications

Bisacodyl 5 mg, gastro-resistant tablets are contraindicated in patients with ileus, intestinal obstruction, acute abdominal conditions including appendicitis, acute inflammatory bowel diseases and severe abdominal pain associated with nausea and vomiting which may be indicative of the aforementioned severe conditions.

Bisacodyl 5 mg gastro-resistant tablets are also contra-indicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.

In case of hereditary conditions that may be incompatible with an excipient of the product (see section 4.4) the use of the product is contraindicated.

#### 4.4 Special warnings and precautions for use

As with all laxatives, Bisacodyl 5 mg gastro-resistant tablets should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation.

Long-term everyday use of stimulant laxatives may harm the intestinal function and should be avoided. If laxatives are needed every day the cause of the constipation should be investigated. This product should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g. renal insufficiency, elderly patients), bisacodyl should be discontinued and only be restarted under medical supervision.

Stimulant laxatives (including bisacodyl) do not help with weight loss (see section 5.1).

Patients may experience haematochezia (blood in stool) that is generally mild and self-limiting.

Dizziness and / or syncope have been reported in patients who have taken bisacodyl. The details available for these cases suggest that the events would be consistent with defecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain related to the constipation, and not necessarily to the administration of bisacodyl itself.

There have been isolated reports of abdominal pain and bloody diarrhea occurring after taking bisacodyl. Some cases have been shown to be associated with colonic mucosal ischaemia.

If the symptoms worsen during the use of medicinal product, a doctor or pharmacist should be consulted

Bisacodyl should not be used by children and adolescents under the age of 12 years.

This product contains a small amount of lactose (64.42 mg) and sucrose (53.00 mg) in each tablet. Patients with rare hereditary problems of galactose intolerance, fructose intolerance,



the Lapp lactase deficiency, sucrase-isomaltase insufficiency or glucose-galactose malabsorption should not take this medicine.

This product contains Tartrazine lake (E102) which may cause allergic reactions.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The concomitant use of antacids and milk products may reduce the resistance of the coating of the tablets and result in dyspepsia and gastric irritation.

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of bisacodyl are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

#### **4.6 Fertility, pregnancy and lactation**

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##### **Pregnancy**

There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy.

##### **Breastfeeding:**

Clinical data show that neither the active moiety of bisacodyl (BHPM or bis-(p-hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating females.

Nevertheless, as with all medicines, bisacodyl should not be taken during pregnancy, especially the first trimester, and during breast feeding unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

##### **Fertility:**

No studies on the effect on human fertility have been conducted.

#### **4.7 Effects on ability to drive and use machines**

No studies on the effects of bisacodyl on the ability to drive and use machines have been performed.

However, patients should be advised that due to a vasovagal response (e.g. to abdominal spasm) they may experience dizziness and / or syncope. If patients experience abdominal spasm they should avoid potentially hazardous tasks such as driving or operating machinery.

#### **4.8 Undesirable effects**

The most commonly reported adverse reactions during treatment are abdominal pain and diarrhoea.

Adverse events have been ranked under headings of frequency using the following convention: Very common ( $\geq 1/10$ ); common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1000$ ,  $< 1/100$ ); rare ( $\geq 1/10000$ ,  $< 1/1000$ ); very rare ( $< 1/10000$ ).

##### Immune system disorders

Rare: anaphylactic reactions, angioedema, hypersensitivity.

##### Metabolism and nutrition disorders

Rare: dehydration.

##### Nervous system disorders

Uncommon: dizziness.

Rare: Syncope.

Dizziness and syncope occurring after taking bisacodyl appear to be consistent with a vasovagal response (e.g. to abdominal spasm, defaecation).

#### Gastrointestinal disorders

Uncommon: haematochezia (blood in stool), vomiting, abdominal discomfort, anorectal discomfort.

Common: abdominal cramps, abdominal pain, diarrhoea and nausea.

Rare: colitis including ischaemic colitis..

This product contains Tartrazine lake (E102) which may cause allergic reactions.

#### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

##### Symptoms

If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium and other electrolytes can occur.

Laxatives when taken in chronic overdose may cause chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalaemia have also been described in association with chronic laxative abuse.

##### Therapy

After ingestion of oral forms of Bisacodyl 5 mg gastro-resistant tablets, absorption can be minimised or prevented by inducing vomiting or gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young. Administration of antispasmodics may be of value.

## **5.0 Pharmacological properties:**

### **5.1 Pharmacodynamic properties**

#### Mechanism of action

Bisacodyl is a locally acting laxative from diphenylmethane derivatives group having a dual action. As a contact laxative, for which also anti-resorptive hydragogue effects have been described, bisacodyl stimulates after hydrolysis in the large intestine, the mucosa of both the large intestine and of the rectum. Stimulation of the mucosa of the large intestine results in colonic peristalsis with promotion of accumulation of water, and consequently electrolytes, in the colonic lumen. This results in a stimulation of defecation, reduction of transit time and softening of the stool. Stimulation of the rectum causes increased motility and a feeling of rectal fullness. The rectal effect may help to restore the "call to stool" although its clinical relevance remains to be established.



As a laxative that acts on the colon, bisacodyl specifically stimulates the natural evacuation process in the lower region of the gastrointestinal tract. Therefore, bisacodyl is ineffective in altering the digestion or absorption of calories or essential nutrients in the small intestine.

### 5.2 Pharmacokinetic properties

Following either oral or rectal administration, bisacodyl is rapidly hydrolyzed to the active principle bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), mainly by esterases of the enteric mucosa.

Administration as an enteric coated tablet was found to result in maximum BHPM plasma concentrations between 4 – 10 hours post administration whereas the laxative effect occurred between 6 – 12 hours post administration. In contrast, following the administration as a suppository, the laxative effect occurred on average approximately 20 minutes post administration; in some cases it occurred 45 minutes after administration. The maximum BHPM-plasma concentrations were achieved 0.5 – 3 hours following the administration as a suppository. Hence, the laxative effect of bisacodyl does not correlate with the plasma level of BHPM. Instead, BHPM acts locally in the lower part of the intestine and there is no relationship between the laxative effect and plasma levels of the active moiety. For this reason, bisacodyl coated tablets are formulated to be resistant to gastric and small intestinal juice. This results in a main release of the drug in the colon, which is the desired site of action.

After oral and rectal administration, only small amounts of the drug are absorbed and are almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide. The plasma elimination half-life of BHPM glucuronide was estimated to be approximately 16.5 hours. Following the administration of bisacodyl coated tablets, an average of 51.8% of the dose was recovered in the faeces as free BHPM and an average of 10.5% of the dose was recovered in the urine as BHPM glucuronide. Following the administration as a suppository, an average of 3.1% of the dose was recovered as BHPM glucuronide in the urine. Stool contained large amounts of BHPM (90% of the total excretion) in addition to small amounts of unchanged bisacodyl.

### 5.3 Preclinical safety data

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



## **6. Pharmaceutical particulars:**

### **6.1 List of Excipients:**

- |                               |   |
|-------------------------------|---|
| 1. Lactose                    | 13. Methylene Dichloride                        |
| 2. Dibasic Calcium Phosphate  | 14. Isopropyl Alcohol                           |
| 3. Maize starch               | 15. Colour Instacoat EN-Sol<br>A31D00042 Yellow |
| 4. Gelatin                    | 16. Calcium Carbonate                           |
| 5. Methyl Paraben Sodium      | 17. Gum Accacia                                 |
| 6. Propyl Paraben Sodium      | 18. Sucrose                                     |
| 7. Talcum                     | 19. Titanium Dioxide                            |
| 8. Magnesium Stearate         | 20. Color Tartrazine Supra                      |
| 9. Sodium Starch glycolate    | 21. Bees Wax                                    |
| 10. Colloidal Silicon Dioxide | 22. Carnauba Wax                                |
| 11. Sodium Lauryl Sulphate    | 23. Carbon Tetrachloride                        |
| 12. Cross Carmellose Sodium   |   |

### **6.2 Incompatibilities:**

None Reported

### **6.3 Shelf-Life:**

36 months from the date of manufacture.

### **6.4 Special Precautions for Storage:**

Store under normal storage condition (15°C to 30°C). Protect from light.

### **6.5 Nature and Contents of Container:**

10X10 tablets packed in blister. Such blister packed in carton with its package insert.  
Such cartons packed in export worthy shipper.

### **6.6 Special precautions for disposal:**

None reported.

## **7. Registrant:**

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- 8. Manufacturer:**  
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- 9. Date of revision of the text :**