SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
SUPOLAKS 5 mg suppository

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each suppository contains

Active substance(s):
Bisacodyl 5 mg

Excipient(s):
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Suppository
Almost white, homogeneous torpedo-shaped suppositories

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
SUPOLAKS is used as a stimulant laxative in the symptomatic treatment of constipation.

SUPOLAKS is used for bowel evacuation for surgery or diagnostic procedures such as x-ray, and instead of laxatives and enemas for all indications.

4.2. Posology and method of administration
Posology/frequency of administration and duration of the treatment:
It should be used with doctor's recommendation in the treatment of chronic or persistent constipation in children aged 10 years and under. SUPOLAKS should not be used in children under 4 years of age.

SUPOLAKS should not be used on a continuous daily basis for more than five days without investigating the cause of constipation.

Short-term relief of constipation:
For children between the ages of 4-10: 1 suppository should be applied for immediate effect.

For diagnostic procedures and preoperative preparation:
It should only be used under medical supervision.
For children aged 4-10 years: 1 suppository should be applied.

In the treatment of constipation, when bowel movements improve, the dosage should be reduced and generally stopped.

Suppositories usually act within 20 minutes (between 10-30 minutes). Rarely, it has been observed to show its laxative effect after 45 minutes. It is administered rectally after opening.

Method of administration:
It is administered rectally.

Additional information for special populations:
Renal/Hepatic failure:
There is no specific use.

Pediatric population:
The method of administration in the pediatric population is given above.
It should not be used in children younger than 4 years old.

Geriatric population:
There is no specific information about its use in the elderly. As a result of clinical studies conducted for over 65 years of age, no specific adverse reactions were found in this age group.

4.3. Contraindications
The use of SUPOLAKS is contraindicated in the following conditions:

- Hypersensitivity to bisacodyl or other components of the product,
- Patients with ileus,
- Patients with intestinal obstruction,
- Patients with acute abdominal conditions including appendicitis,
- Patients with acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting,
- Patients with severe dehydration.

SUPOLAKS should not be used when anal fissures or ulcerative proctitis with mucosal damage are present.

4.4. Special warnings and precautions for use
SUPOLAKS should not be used on a continuous daily basis for more than five days without investigating the cause of constipation.

Prolonged and 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) SUPOLAKS should be discontinued and only be restarted under medical supervision

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

Dizziness and / or syncope have been reported in patients using SUPOLAKS. This has been observed to be associated with a vasovagal response to defecation or abdominal pain.

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

The use of suppositories may lead to painful sensations and local irritation, especially in patients with anal fissures and ulcerative proctitis.

SUPOLAKS should not be used in children younger than 10 years without a doctor's recommendation.

4.5. Interaction with other medicinal products and other forms of interaction
The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of SUPOLAKS are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

Additional information for special populations:
There is no interaction study..

Paediatric population:
There is no interaction study..

4.6. Fertility, pregnancy and lactation
General advise:
Pregnancy category: C

Women of childbearing potential/Birth control (contraception)
No data are available on women of childbearing potential / contraception.

Pregnancy
Animal studies are insufficient with respect to pregnancy / and-or / embryonal / fetal growth / and-or /natal / and-or / postnatal development (see Section 5.3). Potential risk is not known for human.

SUPOLAKS should not be used during pregnancy unless it is necessary.

Lactation
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.

During breastfeeding, if the beneficial effects of SUPOLAKS are higher than other possible risks, it should be used with doctor's advice.

Reproductive ability / Fertility
There has been no research on its effects on reproductive ability.

4.7. Effects on ability to drive and use machines
Not reported.

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 common undesirable effects during treatment are abdominal pain and diarrhea.

The specified undesirable effects are classified according to the following rule:
Very common (≥1/10); common (≥1/100 to <1/10); not common (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (cannot be estimated based on available data).

Immune system disorders
Rare: Anaphylactic reactions, 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
Common: Abdominal cramps, abdominal pain, nausea and diarrhoea.
Uncommon: Haematochezia (blood in stool), vomiting, abdominal discomfort, anorectal discomfort.
Rare: Colitis.

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. Healthcare professionals are asked to report any suspected adverse reactions via Turkish Pharmacovigilance Center (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel.: 0 800 314 00 08; fax: 0 312 218 35 99).

4.9. Overdose and treatment
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 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
Supportive and symptomatic treatment is indicated in case of overdose in treatment with SUPOLAKS. Correction of electrolytic imbalance and fluid replacement may be required. The dose of SUPOLAKS should be reduced and usually stopped.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Contact laxatives.
ATC Code: A06AG02

Stimulant laxatives show their effects by directly stimulating peristaltic movements with local irritation on the intestinal mucosa. In this way, these increase intestinal motility. Recent studies show that blocking of fluid and electrolyte absorption in the intestine also plays a role in the colon

emptying effect of bisacodil. This effect causes fluid accumulation in the intestinal lumen and a laxative effect.

5.2. Pharmacokinetic properties
General characteristics
Absorption:
In the use of suppositories, the laxative effect is observed approximately 20 minutes after administration, and rarely 45 minutes after administration.
In suppository applications, BHPM plasma concentration reaches its maximum after 0.5-3 hours. Therefore, there is no correlation between BHPM plasma level and laxative effect. BHPM affects only a small part of the intestine locally and there is no relationship between laxative effect and plasma level.

Distribution:
After rectal administration, bisacodyl is rapidly hydrolyzed to the active moiety bis- (p-hydroxyphenyl) -pyridyl-2-methane (BHPM), mainly by esterase of the enteric mucosa.

Biotransformation:
After rectal administration, a very small portion of the drug is absorbed and fully conjugated with the intestinal wall and liver, converting to inactive BHPM glucuronide.

Elimination:
The plasma elimination half-life of BHPM was measured as approximately 16.5 hours.
In suppository application, an average of 3.1% of the dose is found in the urine as BHPM glucuronide.

5.3. Preclinical safety data
Studies in rats and mice revealed that it does not show carcinogenic effects. Bisacodyl has no mutagenic or genotoxic potential.
Bisacodyl has not been studied in descriptive animal toxicity tests. Induction of cell proliferation in the intestinal epithelium was observed after administration of bisacodyl in animal trials. 0.3% bisacodyl supplementation for 32 weeks stimulated the formation of stones and epithelial proliferative lesions in the rat bladder.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Witepsol

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature below 25ºC.
Store in the cardboard box.

6.5. Nature and contents of container
Opaque PVC / PE strip

Each carton contains 5, 10 or 20 suppositories.

6.6. Special precautions for disposal and other handling
Any unused medicinal products or waste materials should be disposed of in accordance with "Regulation for the Disposal for Medicinal Waste" and "Regulation for the Control of Packaging and Packaging Waste".

7. MARKETING AUTHORISATION HOLDER
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8. MARKETING AUTHORISATION NUMBER
2016/658

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorization: 09.09.2016
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT
07.03.2019