

Composition:

Each EGESTALAX Film Coated Tablets contains:
Docusate Sodium 50 mg and Sennosides 8.6 mg.

Pharmaceutical Group:

Laxatives and Stool Softeners.

Pharmacological Properties & Mechanism of Action:

Docusate Sodium is an anionic softening agent, which acts as a stool softener by lowering surface tension and allowing the penetration of accumulated dry, hard stool by water and salts. Docusate Sodium also has a tonic effect on the intestines.

The sugar portion of Sennosides is removed by bacteria in the large intestine, releasing the active anthrone portion. Which leads to stimulation of peristalsis through the submucosal and enteric nerve plexuses.

Pharmacokinetics:

Docusate Sodium exerts its clinical effect in the gastrointestinal tract. There is some evidence that Docusate Sodium is absorbed and excreted in the bile. There is also evidence that Docusate Sodium is able to enhance the absorption of some concomitantly administered compounds. The action of Sennosides is colon-specific and does not depend on systemic absorption. β -O-linked glycosides (Sennosides) are not absorbed in the upper intestine and are not broken down by human digestive enzymes. They are converted by large intestine bacteria to the active metabolite (rhein anthrone). After oral administration of Sennosides, approximately 3-6% of the metabolites are excreted in the urine, and some are excreted in bile.

Indications:

Relieves occasional constipation (irregularity) and generally produces bowel movement in 12- 6 hours.

Contraindications:

EGESTALAX is contraindicated in the following cases:

- Hypersensitivity to the active ingredients or any of the excipients.
- Cases of intestinal obstruction.
- Appendicitis.
- Inflammatory bowel diseases (such as Crohn's disease, ulcerative colitis).
- Abdominal pain of unknown cause.
- Nausea and vomiting.
- Gastrointestinal bleeding.
- Rectal bleeding.
- Coadministration with mineral oils unless otherwise directed by the physician.

Warnings & Precautions:

You should consult a doctor before use if you have a sudden and persistent change in bowel habits for more than two weeks.

Pregnancy & Lactation:

It is not recommended to use EGESTALAX during

pregnancy or lactation due to the lack of sufficient data regarding the effects on the fetus and infant.

Drug Interactions:

- Docusate Sodium should not be taken in conjunction with mineral oil laxatives such as liquid paraffin.
- Hypokalemia (resulting from long-term laxative intake) enhances the action of cardiac glycosides and interferes with antiarrhythmic drugs.
- Concomitant use with other drugs that cause hypokalemia (e.g. diuretics, adrenal corticosteroids and licorice root) may lead to increased electrolyte imbalance.

Side Effects:

Hypersensitivity reactions (itching, urticaria, rash), abdominal pain and cramps may occur. Chronic use may lead to disturbances in the balance of water and electrolytes.

Driving & Using Machines:

It is not known whether EGESTALAX affects the patient's ability to drive or use machines.

Dosage & Administration:

It is preferable to take EGESTALAX at bedtime or as directed by your doctor.

Age	Starting Dose	Maximum Dose
Adults and children 12 years of age or older	2 tablets once daily	4 tablets twice daily
Children aged 6 to under 12 years	one tablet once daily	two tablets twice daily
Children aged 2 to under 6 years	half a tablet once daily	one tablet twice daily
Children under 2 years of age	Ask a doctor	Ask a doctor

Overdose:

Overdose may cause excessive loss of fluids and electrolytes.

Symptoms: The main symptoms of overdose/misuse are severe pain, severe diarrhea and consequently loss of fluids and electrolytes, which must be replaced. Diarrhea in particular may cause potassium depletion, which may lead to heart disorders and myasthenia gravis.

Treatment: Treatment should be supportive with adequate fluid intake. Electrolytes, especially potassium, should be monitored. This is especially important in elderly.

Storage

Store at a temperature between 15-30° C.

Keep out of reach of children.

Packaging:

Each EGESTALAX Carton Box contains 20 Film coated tablets in two blister strips.

-A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
-The doctor and the pharmacist experts in medicine, it's benefits and risks.
-Do not repeat the same prescription without consulting your doctor.
-KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
-Council of Arab Health Ministers- Union of Arab Pharmacies

Revapharma for Pharmaceutical Industries - Idlib - Syria

