



FORTASEC Capsules

Read all of the package insert with care before starting to take this medicine.

- Keep this package insert. You may need to reread it.
- Ask your doctor or pharmacist if you have any questions.
- This medicine has been prescribed to you personally and you should not give it to other people. It may be harmful to them, even if their symptoms are the same as yours.

This package insert explains:

1. What FORTASEC Capsules is and what it is used for
2. Before taking FORTASEC Capsules
3. How to take FORTASEC Capsules
4. Possible adverse effects
5. Storing FORTASEC Capsules

FORTASEC Capsules

- The active ingredient of FORTASEC Capsules is loperamide. Each capsule contains 2 mg of loperamide

- The excipients are: lactose, talc, magnesium stearate and silicon dioxide, q.s.

Manufacturer: Laboratorios Dr. Esteve, S.A. Avda. Mare de Déu de Montserrat, 221 - 08041 Barcelona

1. WHAT IS FORTASEC Capsules AND WHAT IS IT USED FOR

FORTASEC Capsules is an antidiarrheal that reduces bowel movements and secretions, decreasing the production of liquid stools. Each box contains 10 and 20 capsules.

FORTASEC Capsules is used for the symptomatic treatment of acute and chronic diarrheal conditions.

2. BEFORE TAKING FORTASEC Capsules

Do not take FORTASEC Capsules,

- If you are allergic to loperamide or any of this medicine's components;
- Do not give to children under 2 years of age
- If blood appears in your stools or you have a high fever (above 38°C)
- If you suffer from bowel inflammation (e.g. ulcerative colitis or pseudomembranous colitis associated with antibiotic therapy)
- If you suffer from constipation or abdominal swelling

Although Fortasec stops diarrhea, it does not treat its cause. Therefore, as soon as it is possible, the diarrhea's cause must also be treated.

Take particular care

Patients suffering from diarrhea must drink plenty of liquid to prevent dehydration. The symptoms of dehydration are: dry mouth, excessive thirst, decrease in urine output, wrinkled skin, dizziness, confusion. This is particularly important in children and elderly people.

- In cases of acute diarrhea, stop treatment and see your doctor if no improvement is observed within 48 hours.
- Patients with liver problems should ask their doctor before taking this medicine.
- AIDS patients who are being treated with Fortasec for diarrhea should stop treatment as soon as the first signs of abdominal swelling or distension appear.

Pregnancy

Safe use of loperamide during pregnancy has not been established. Therefore, you are advised to not use this medicine without asking your doctor beforehand.

Ask your doctor or pharmacist before taking any medicine.

Breastfeeding

Breastfeeding women should not use this medicine without asking their doctor beforehand.

Ask your doctor or pharmacist before taking any medicine.

Driving or using machines

Although loperamide is not expected to have any effects on these activities, you are advised to not drive or handle machinery if you feel tired, dizzy or drowsy.

Taking other medicines

- Tell your doctor or pharmacist if you are taking or have recently taken any other medicine

- including OTC medicines.

They may enhance the action of the anticholinergics and bowel peristalsis inhibitors.

3. HOW TO TAKE FORTASEC Capsules

FORTASEC Capsules is taken orally.

Children aged over 5: 1 capsule as a starting dose followed by 1 capsule after every diarrheal stool. In children, the maximum dose should be related with the body weight.

Child's weight	Maximum number of capsules per day
Above 14 kg	Maximum 2 capsules
Above 20 kg	Maximum 3 capsules
Above 27 kg	Maximum 4 capsules
Above 34 kg	Maximum 5 capsules
Above 40 kg	Maximum 6 capsules
Above 47 kg	Maximum 7 capsules
Above 54 kg	Maximum 8 capsules

Adults: 2 capsules as a starting dose followed by 1 capsule after every diarrheal stool up to a maximum of 8 capsules per day.

If you have the impression that the effect of FORTASEC Capsules is too strong or too weak, ask your doctor or pharmacist.

Instructions for correct use

Swallow the capsules of FORTASEC with a full glass of water.

If you take more FORTASEC Capsules than you should

If you have taken more FORTASEC Capsules than you should, ask your doctor or pharmacist immediately.

In the event of overdose or accidental intake, contact the Toxicological Information Service, telephone number 91.562.04.20, stating the name of the medicine and the quantity taken.

4. POSSIBLE ADVERSE EFFECTS

Like all medicines, FORTASEC Capsules may have adverse effects.

The side effects that have been described are:

Skin: hypersensitivity reactions such as skin rash and urticaria.

Gastrointestinal: a number of adverse effects have been described which are normally difficult to differentiate from the diarrheal syndrome, such as: abdominal pain or distension, nausea, vomiting and flatulence. Occasionally, cases of constipation have been observed.

Urological: urine retention has been described on rare occasions.

Central Nervous System: symptoms such as tiredness, drowsiness or dizziness, and dry mouth have been observed on occasion.

General: swollen face, breathlessness

If you observe these or any other adverse reaction not described above, ask your doctor or pharmacist.

5. STORAGE OF FORTASEC CÁPSULACAPSULES

Keep FORTASEC Capsules out of children's reach and sight

Store in the original package at room temperature (between 15°C and 30°C).

Expiry

Do not use FORTASEC Capsules after the expiry date printed on the package.

OTHER PRESENTATIONS

Fortasec Solution. Bottle with 100 ml

This package insert was approved on: December 2003

ESTEVE

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