

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

FIBOTAB

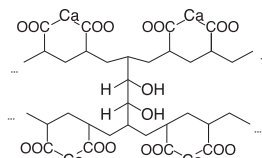
(Calcium Polycarbophil Tablets)

COMPOSITION

Each film coated tablet contains :
Calcium Polycarbophil U.S.P. 625 mg
equivalent to Polycarbophil 500 mg
Colours : Red Oxide of Iron & Titanium Dioxide

DESCRIPTION

Calcium polycarbophil is the calcium salt of polyacrylic acid crosslinked with divinyl glycol. It is chemically and physiologically inert. It has the following chemical structure.



Calcium Polycarbophil

MECHANISM OF ACTION

Calcium polycarbophil possesses exceptionally high water-binding capacity, is not absorbed, does not interfere with the activity of digestive enzymes or intestinal absorption, possesses satisfactory stability, is physiologically inert, and does not cause gastro-intestinal irritation. Calcium polycarbophil possesses little chelating ability and thus does not remove essential metabolites, vitamins or minerals, even when fed in effective doses for long periods of time. It has negligible ion-exchange capacity for sodium, being on the order of 1-3%.

In constipation, Calcium polycarbophil absorbs liquid in the intestines and swell to form a soft bulky stool. The bulky mass stimulates the intestinal muscles speeding stool transit time through the colon.

In diarrhea, the action of calcium polycarbophil depends on its capacity to absorb free fecal water and produce a formed gel within the lumen of the hypermotile bowel or that bowel unable to absorb water due to a pathological alteration of the mucosa. Calcium polycarbophil exhibits relatively marked capacities for absorption and retention of water *in vitro*.

INDICATIONS

For the relief of occasional constipation
For relief of diarrhea due to functional or organic cause
For improving irritable bowel symptoms in adults

CONTRAINDICATIONS

'Calcium polycarbophil' tablets are contraindicated in patients who are allergic to bulk laxatives, patients who have difficulty swallowing and in those who have an intestinal blockage or impacted stool.

WARNINGS & PRECAUTIONS

As with all bulk-forming agents, calcium polycarbophil should not be used in patients with stenotic lesions compromising the lumen of the gastrointestinal tract.

Don't take if :

You have symptoms of appendicitis, inflamed bowel or intestinal blockage.

You have missed a bowel movement for only 1 or 2 days

When abdominal pain, nausea or vomiting are present unless directed by a doctor.

If you experience chest pain, vomiting, or difficulty swallowing or breathing after taking this product, seek immediate medical attention

Before you start, consult your doctor :

If you have diabetes

If you have a laxative habit

If you have rectal bleeding

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition.

If you notice a sudden change in bowel habits that persists over a period of 2 weeks

If you have difficulty swallowing

Taking this product without enough liquid may cause it to swell, block your throat or esophagus and may cause choking.

If you take other laxatives

Prolonged use:

Don't take for more than 1 week unless under a doctor's supervision.

May cause laxative dependence.

Skin & sunlight:

No problems expected.

Driving, piloting or hazardous work:

No problems expected.

Discontinuing:

May be unnecessary to finish medicine.

Follow doctor's instructions.

Others:

Don't take to "flush out" your system or as a "tonic".

Use in Pregnancy, Nursing Mothers And Children

Pregnancy

During pregnancy, bulk-formers that contain a large amount of sodium or sugar may increase blood pressure or cause water retention. Avoid if possible. Consult doctor.

Nursing Mothers

No problems expected. Consult doctor.

Pediatric Use

This product is not recommended for children under 12 yrs old unless specifically directed by a doctor.

Geriatric Use

Adverse reactions and side effects may be more frequent and severe than in younger persons.

ADVERSE REACTIONS

Some of the adverse reactions with calcium polycarbophil are mild such as a stomach upset, which may be avoided by taking the medication with food.

Minor reactions may go away on their own but if they persist, contact the physician. For major reactions, the patient should contact the physician immediately.

Following are the observed side effects:

Life-threatening:

None expected.

Minor:

Bloating, diarrhea, rumbling sounds, nausea, mild abdominal cramps

Major:

Severe abdominal pain, vomiting, trouble swallowing

Rare:

Itchy skin, rash, intestinal blockage, asthma

DRUG INTERACTIONS

Diuretics, Potassium-sparing or Potassium supplements : Chronic or overuse of this laxative can reduce potassium by promoting potassium loss from the intestines. It may also interfere with the potassium-retaining effects of potassium sparing diuretics.

Prescription Medications: Calcium Polycarbophil may affect how other medications work. If taking prescription medications, consult with your doctor before using this drug. After taking a prescription medication, wait at least two hours before taking calcium polycarbophil.

Tetracycline antibiotics (oral):

Calcium polycarbophil used concomitantly with tetracyclines may decrease the absorption of the drug because of a possible formation of non-absorbable complexes. After taking tetracycline, wait at least one to two hours before consuming calcium polycarbophil. Calcium polycarbophil may reduce the effect of digitalis and salicylate (including aspirin). No interaction is expected with alcohol, beverages, cocaine, food, marijuana and tobacco.

Calcium Polycarbophil should not be taken with antacids, divalent/trivalent cations and phosphate supplements.

TOXICOLOGICAL PROPERTIES

Teratology

No evidence of any teratogenic potential, toxicity, or adverse effects on fertility or reproduction was noted in male and female rats fed calcium polycarbophil for 60 days at doses of 0, 5, and 10% of the diet. No adverse effects were observed on viability, growth, behavior, appearance, vital organs, or hematology in newborn rat pups fed calcium

polycarbophil for 21 days at dosage levels of 0,4, and 8 mg/day. In a study of pregnant rats, animals were divided into several groups: a negative control group receiving a basal diet, polycarbophil groups receiving calcium polycarbophil in the diet at levels of 1, 5, and 10% (of polycarbophil), and a positive control group receiving carboxymethyl cellulose at a level equal to the highest dose of calcium polycarbophil.

The positive control group showed a marked increase in the number of soft stools compared with the negative control group.

No biological differences were observed in appearance, behavior, mean maternal body weight, mean maternal feed consumption, mean number of viable fetuses, post-implantation losses, total implantations, corpora lutea, fetal sex distribution, or mean fetal body weights in the calcium polycarbophil-treated groups.

DOSAGE AND ADMINISTRATION

Daily dose of 4-5 g is recommended in adults.

How to take:

Swallow Fibotab tablets with 8 oz. cold liquid. Drink 6 to 8 glasses of water each day in addition to the one with each dose.

When to take:

At the same times each day.

If you forget a dose:

Take as soon as you remember.

Resume regular schedule.

Time lapse before drug works:

May require 2 or 3 days to begin, then works in 12 to 24 hours.

OVERDOSAGE

No cases of acute overdose with calcium polycarbophil have been reported.

Overdose is unlikely to threaten life. If person takes much larger amount than prescribed, consult your doctor immediately.

EXPIRY DATE

Do not use later than the date of expiry.

STORAGE

Store below 30°C.

PRESENTATION

Fibotab is available in a strips of 10 tablets



Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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Teh. Nalagarh, Dist. Solan (H.P.), INDIA.