

FESTAL® N

Pancreatin Tablets

THERAPEUTIC CATEGORY

Digestive Enzymes

COMPOSITION

Each enteric-coated tablet of Festal® N contains:

Pancreatin I.P. 212.5 mg equivalent to:

Lipase activity ...6000 F.I.P units

Amylase activity ...4500 F.I.P units

Protease activity ...300 F.I.P units

THERAPEUTIC INDICATIONS

Digestive complaints, such as gastric pressure, feeling of repletion, or flatulence caused, for example, by heavy, mainly fatty or unaccustomed food, excessive food intake, or not chewing food sufficiently. Digestive disorders due to impairment of pancreatic function.

DOSAGE AND ADMINISTRATION

1-2 tablets 3 times a day should be taken 30 minutes before meals or during meals. They should not be chewed, but swallowed whole with a little fluid if required. The dosage can be increased if necessary.

SAFETY-RELATED INFORMATION

Contraindications: Hypersensitivity to animal pancreatic enzymes.

Precautions & Warnings: Consult doctor if the complaints persist or become worse, if additional symptoms occur, or if taking the medicine relatively frequently over a prolonged period. Festal N should not be taken during an attack of acute pancreatitis or during an acute exacerbation of chronic pancreatitis. During the subsequent recovery phase, when the diet is being gradually rebuilt, Festal N should be taken only if advised by the doctor.

Pregnancy & Lactation: May be taken during pregnancy and lactation by taking into consideration the benefit/risk ratio.

Adverse Reactions: Hypersensitivity reactions such as reddening of the skin, sneezing or lacrimation may occur. Diarrhoea, nausea and abdominal pain, sometimes of colicky type, may be experienced, especially by patients taking high doses. Irritation around the anus has occurred in isolated cases. Very high dosage, as may be necessary in such conditions as mucoviscidosis, may lead to elevated uric acid levels. Children with mucoviscidosis - especially when treated with high doses of pancreatin enzymes - narrowing of certain intestinal regions (ileocecal region, ascending colon) has been reported in isolated cases.

For full prescribing information write to Sanofi India Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400 072.

Created : Feb 2012

Sources:

Turkish PI of Festal N dated Feb 2012