

Package leaflet: Information for Patient

Tibrolin[®]

(Trypsin, Bromelain and Rutoside Trihydrate Tablets)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor, pharmacist or nurse.
3. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tibrolin[®] Tablets is and what it is used for
2. What you need to know before you are given Tibrolin[®]
3. How to use Tibrolin[®]
4. Possible side effects
5. How to store Tibrolin[®]
6. Contents of the pack and other information

1. What is Tibrolin[®] and what it is used for

Tibrolin[®] is a combination enzyme supplements which contains a mix of enzymes such as bromelain (from pineapple), trypsin, and rutoside (a bioflavonoid).

1. **Bromelain:** Bromelain is a mixture of proteolytic enzymes derived from the pineapple plant. It is believed to have anti-inflammatory properties by reducing the production of pro-inflammatory cytokines and promoting the breakdown of proteins that contribute to swelling and inflammation.
2. **Trypsin:** Trypsin is a protein-digesting enzyme naturally produced by the pancreas. It aids in the digestion of proteins and has been used in supplements to support the body's natural inflammatory response.
3. **Rutoside:** Rutoside, also known as rutin, is a flavonoid found in certain fruits and vegetables. It is an antioxidant and is thought to help strengthen capillaries and reduce inflammation.

Tibrolin[®] is commonly used for the following purposes:

- **Joint Health:** It is often taken to support joint health and mobility, particularly in conditions involving inflammation such as osteoarthritis.

- **Inflammatory Conditions:** Due to its anti-inflammatory properties, Tibrolin® may be used to help reduce swelling and inflammation in various parts of the body especially post-operatively.
- **Injuries:** Some athletes and active individuals use Tibrolin® to aid in recovery from injuries or to alleviate muscle soreness after intense exercise.

The enzymes bromelain and trypsin reduce both edema of inflammatory origin, as well as swelling accompanying trauma or surgery.

2. What you need to know before you are given Tibrolin®

Do not use Tibrolin® if:

you are allergic to Tibrolin® or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given **Tibrolin®** if:

- you have hereditary coagulation disorder (e.g. haemophilia)
- you have liver problems
- The combination cannot replace an ongoing antibiotic therapy.
- Temporary reduction of dose advised if there is exacerbation of symptoms on initial therapy.

Other medicines and Tibrolin®

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Currently there are no reports of incompatibility of Tibrolin with other concomitant medications has been reported.

Pregnancy, breast-feeding and fertility

If you are pregnant, think that you might be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this medicine. They will decide whether or not you are given this medicine while you are pregnant. Tell your doctor if you are breast-feeding, before being given this medicine. He/she will decide whether or not you can keep breast-feeding, while you are given F Tibrolin®.

Tibrolin® should be used with caution during pregnancy & breast feeding.

Driving and using machines

It is not known whether Tibrolin tablet alters the ability to drive. Do not drive if you experience any symptoms that affect your ability to concentrate and react

3. How to use Tibrolin®

Adults: 1 to 2 tablets two or three times daily by oral route. Tablets should be swallowed on empty stomach at least 30 min before meals or 2 h after meals. Tablet should be swallowed whole & not to be broken, crushed or chewed.

If you have more Tibrolin® than you should

If you think you have been given too much Tibrolin® or if you are agitated, talk to your doctor or nurse straight away.

If you forget to have Tibrolin®

Take the forgotten tablet as soon as you remember. Take the next tablet 24 hours after this and continue taking your tablets every 24 hours. Do not take a double dose to make up for a forgotten tablet.

If you stop having Tibrolin®

Do not stop having this medicine without first talking to your doctor, pharmacist or nurse. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Generally, well tolerated, even during prolonged high doses were observed in most cases, side effects.

Occasionally may appear insignificant change in consistency, colour and odour of stool.

Rare side effects are: headache, hunger, and increased sweating.

During high-dose were observed feelings of fullness, impoundment, occasional nausea. This feeling can be avoided by dividing the total dose during the day.

Rarely occurring allergic reactions (skin rash) disappear after discontinuation.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top end of the home page.

Website: <https://www.zuventus.com/drug-safety-reporting>

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

5. How to store Tibrolin®

Store in a dry & dark place, at a temperature not exceeding 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label of the vial. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Tibrolin® contains:

Each enteric coated tablet contains: The active substances are Trypsin (48mg), Bromelain (90mg) and Rutoside Trihydrate (100mg).

What Tibrolin® looks like and contents of the pack

Pack size: A blister strip of 10 tablets.

Marketing Authorisation Holder

Marketing Authorisation Holder

Zuventus Healthcare Ltd
A joint venture of Emcure
5119, Oberoi Garden Estates, D-Wing,
Chandivali, Andheri (E), Mumbai 400 072.
TM - Trade Mark Owners.

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