



## Gastroprotect Raft 500 mg/ 267 mg/ 160 mg/ 10 ml oral suspension

*Sodium alginate/Sodium hydrogen carbonate/Calcium carbonate*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### What is in this leaflet

1. What Gastroprotect Raft is and what it is used for
2. What you need to know before you take Gastroprotect Raft
3. How to take Gastroprotect Raft
4. Possible side effects
5. How to store Gastroprotect Raft
6. Contents of the pack and other information

#### 1. What Gastroprotect Raft is and what it is used for

Sodium alginate contained in Gastroprotect Raft, forms a protective layer on top of the stomach contents ("raft" floating on the stomach contents) preventing reflux of stomach contents back into the esophagus, whereas sodium hydrogen carbonate and calcium carbonate neutralize hydrochloric acid in the stomach. As a result of this, stomach pain, burning sensation and discomfort after meals are relieved.

Gastroprotect Raft is used for relief and treatment of heartburn, impaired digestion, reflux of stomach contents back into the esophagus after meals in the event of the so called gastroesophageal reflux disease incl. during pregnancy

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### 2. What you need to know before you take

##### Gastroprotect Raft

**Do not use** Gastroprotect Raft if you are allergic to sodium alginate, sodium hydrogen carbonate, calcium carbonate or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

Talk to your doctor or pharmacist before using Gastroprotect Raft.

You must talk to your doctor or another healthcare

professional if, in spite of the treatment, you do not feel better or you feel worse after 7 days.

#### Children and adolescents

This medicine is not recommended for use by children under 6 years of age.

The drug effect may be reduced if the level of hydrochloric acid in the stomach is too low. Talk to your doctor if you are aware that you have reduced level of hydrochloric acid in the stomach.

#### Other medicines and Gastroprotect Raft

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In the event of concomitant administration with other medicines, Gastroprotect Raft may reduce their intestinal absorption and their effect accordingly, therefore a time interval of at least 2 hours should be considered between intake of this medicinal product and the administration of other medicinal products.

This refers mostly to medicinal products of the following groups: H2-blockers (reducing stomach acidity), some antibiotics (tetracyclines, ketoconazole, fluoroquinolones), drugs for treatment of cardiac diseases (digoxin, beta-blockers), iron salts, neuroleptics, thyroxine, penicillamine, glucocorticosteroids, chloroquines, diphosphonates.

#### Gastroprotect Raft with food, drink and alcohol

No restrictions.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine can be used by pregnant women.

The active substances are not excreted in breast milk, therefore the product can be used during breast-feeding.

#### Driving and using machines

Gastroprotect Raft has no influence on the ability to drive and use machines.

#### Gastroprotect Raft contains sodium, calcium carbonate, methyl and propyl parahydroxybenzoate

This medicinal product contains the following in 10 ml suspension (1 dose):

- 141 mg (6.2 mmol) sodium. This should be taken into account in patients on low sodium diet.
- 160 mg (1.6 mmol) calcium carbonate which should be taken into account in patients with increased calcium levels in the blood, and those with kidney stones.

If you suffer from serious kidney or heart disease, consult your doctor as these salts may affect such diseases.

The product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions, incl. delayed ones.

### 3. How to take Gastroprotect Raft

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children 12 years and over: 10 ml -20 ml after meals, several times daily; the last dose should be given before bedtime.

Maximum daily dose: 80 ml

Children 6 to 12 years: 5.0 -10 ml after meals, several times daily; the last dose should be given before bedtime.

Children below 6 years: this medicinal product is not recommended for use.

#### Elderly

No dose modification is necessary.

This product is for oral administration.

### If you take more Gastroprotect Raft than you should

The likelihood of an overdose is minimal. The symptoms of overdose are abdominal discomfort and bloating.

If you take more medicine than you should, it probably will not harm you; however, if you have any complaints, you should seek medical advice.

### If you forget to take Gastroprotect Raft

If you have missed a dose, take it as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

### If you stop taking Gastroprotect Raft

Treatment should not be stopped too early because you may not achieve the desired results.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rare (less than 1 in 10 000) adverse reactions may occur: urticaria (hives), allergic reactions incl. severe allergic reaction which causes difficulty breathing, wheezing, dizziness, swelling of the face or throat.

### Reporting of suspected side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

### 5. How to store Gastroprotect Raft

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

Store below 30°C in the original package. Do not refrigerate or freeze.

Do not use this medicine after the expiry date which is stated on the carton after EXP:

The expiry date refers to the last day of that month.

Shelf life after first opening of the bottle: 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Gastroprotect Raft contains

- The active substances in 10 ml (1 dose) are: sodium alginate 500 mg, sodium hydrogen carbonate 267 mg, calcium carbonate 160 mg;
- The other ingredients (excipients) are: carbomer 974 P, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), saccharin sodium (E954), mint flavour (mixture of aromatic substances, menthol and maltodextrin), sodium hydroxide, purified water;

#### What Gastroprotect Raft looks like and contents of the pack

The medicinal product Gastroprotect Raft is an off-white to cream coloured suspension with the odour and flavour of peppermint.

The medicinal product is packed in bottles or sachets.

150 ml oral suspension in amber glass bottles.

Pack with one bottle and a 5 ml measuring spoon.

10 ml oral suspension in a multi-layer foil sachet.

10 or 20 sachets in a cardboard outer carton.

#### Marketing Authorisation Holder and Manufacturer:

Adipharm EAD  
130 Simeonovsko shosse Blvd  
1700 Sofia  
Bulgaria

**This leaflet was last revised in**  
12/2019