

 PACKAGE LEAFLET:  
Information for the patient

## **ANABOFARMA**

### **Tablets – 5 mg**

*(Methandienone)*

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **What is in this leaflet:**

1. What Anabofarma is and what it is used for
2. Before you take Anabofarma
3. How to take Anabofarma
4. Possible side effects
5. How to store Anabofarma
6. Further information

#### **1. WHAT ANABOFARMA IS AND WHAT IT IS USED FOR**

Anabofarma contains the active substance methandienone (methandrostenolone). It has anabolic effects, which are more pronounced than its androgenic effects. This preparation increases protein synthesis, prevents calcium and nitrogen removal from the kidneys and opposes prohibitive katabolic side effects caused by treatment with adrenocortical hormones with a prolonged action. Methandrostenolone incites formation of bone basic material, a necessary condition for increasing skeletal calcium reserves. The anabolic effect appears with increased appetite, with weight gain and improvement of the overall conditions.

Anabofarma - tablets - 5 mg - is used in syndromes and diseases requiring the anabolic and catabolic effects and a general reconstructive action, such as: convalescence after severe infections, after surgeries and labor; general weakness after chronic infectious diseases; general weakness and fatigue; insufficient weight; pathological weakness; cachexy; hyperthyroidism; osteoporosis; bone damage process; delayed fractures consolidation; myodystrophy; protein loss from the kidneys, intestines and skin (nephrosis, intestinal protein loss syndrome, burn, etc.); an aid of some therapeutic precaution, such as corticotherapy, cytotoxic treatment, radiotherapy. It has been used in infants growth disorders, in children and adolescents.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANABOFARMA**

##### **Do not take Anabofarma:**

- if you are hypersensitive (allergic) to methandienone or to any of the other ingredients of Anabofarma;
- if you suffer from prostatic cancer;

- if you suffer from breast cancer;
- if you have hypercalcemia (high level of calcium in blood);
- if you have hypercalciuria (high level of calcium in urine);
- if you have severe liver or renal disease;
- during pregnancy;
- during breastfeeding.

Anabofarma is considered unsafe in the pediatric age. If you think you have any of the situations mentioned above, do not take it, talk to your doctor first and follow the given advice.

##### **Warning and precautions**

Tell your doctor before taking Anabofarma:

- if you are hypersensitive to other drugs, especially if they are in the same group of medicines with Anabofarma.

Anabofarma should be used with caution in patients with:

- cardiovascular disorders;
- impaired kidney or liver function;
- epilepsy;
- migraine;
- diabetes or other conditions that can be aggravated by possible fluid retention.

##### **Taking other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Inform your doctor if you are taking one of the following drugs:

- coumarinic and indanedionic anticoagulants;
- oxyphenbutazone, because methandienone can increase its plasma concentrations;
- insulin, because methandienone can enhance the blood glucose-lowering effects of insulin.

These drugs may be affected by Anabofarma, or may affect the way it acts. You may need to use different dosage of this drug or take other drugs. Your doctor or pharmacist will advise you.

##### **Taking Anabofarma with food and drinks**

There is no evidence that this drug may interact with food and drinks.

##### **Pregnancy**

Tell your doctor or pharmacist if you are pregnant, think you may be pregnant or are planning to have a baby. Like most drugs of this type, it is not recommended to take Anabofarma during pregnancy. Your doctor or pharmacist will discuss about the risks and benefits of taking it during pregnancy.

##### **Breastfeeding**

Tell your doctor or pharmacist if you are breast-feeding. This medicine passes into breast milk. Your doctor or pharmacist will discuss about the risks and benefits of taking it if you are breast-feeding or are planning to breast-feed your baby.

##### **Driving and using machines**

Be careful when driving or operating machinery until you see how Anabofarma affects you, anyway there are no data that show that Anabofarma affects the ability to drive.

##### **Important information about some of the ingredients of Anabofarma**

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

##### **3. HOW TO TAKE ANABOFARMA**

Always take Anabofarma tablets only as your doctor has told you. If you feel that the effects of Anabofarma are too strong or too weak, talk to your doctor or pharmacist.

The tablets should be taken at the same time every day.

The average initial dose in adults is 10 mg per day (5 mg, twice daily). The maintenance dose is usually 5 mg per day. In severe disease higher daily doses can be used, e.g. 20 - 30 mg per day, in divided doses.

However, your doctor may advise you to take another dose depending on your condition and your response to the drug.

Your doctor may ask you to take Anabofarma for a longer time. Ask your doctor for advice if you are not sure for how long it should be taken.

Anabofarma tablets should be swallowed whole, with a glass of water.

##### **If you take more Anabofarma**

If you take more Anabofarma than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

##### **If you forget to take Anabofarma**

If you forget to take one dose, take the next dose in its usual time.

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

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

##### **4. POSSIBLE SIDE EFFECTS**

All medicines may cause side effects. Sometimes they are serious, most of the time they are not. Do not get alarmed by this list of possible side effects. You may not get any of them.

Tell your doctor if any of the following side effects concerns you:

- adverse effects on its metaboliser activity such as: increased nitrogen, sodium and water retention, edema;
- increased skin vascularization,
- hypercalcemia;
- glucose tolerance impairment;
- increased bone growth and skeletal weight;
- jaundice and cholestatic hepatitis;
- hepatic tumors;
- in males, testicular atrophy, oligo and azospermia, prostatic hypertrophy, gynaecomastia, priapism; in females, virilism such as hirsutism, deepening of the voice, alopecia, menstrual disorders; in both sexes, libido modifications, prepubertal acne, ossification of growth cartilage, poliglobulia, hepatotoxicity, gastrointestinal disorders.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

##### **5. HOW TO STORE ANABOFARMA**

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

Do not use Anabofarma after the expiry date which is stated on the pack.

Do not store above 25°C!

##### **6. FURTHER INFORMATION**

###### **What Anabofarma contains**

The active substance is methandienone (methandrostenolone).

Each tablet contains 5 mg methandienone.

The other excipients are: maize starch, lactose monohydrate, gelatin, magnesium stearate.

###### **Contents of the pack**

Box with 30 tablets.

###### **Explanatory of the illustration icons on the packaging:**



According to medical prescription.



Content.



Warning.



Should not be used during pregnancy.



Tablet shape.

###### **Marketing authorisation holder and manufacturer**



**PROFARMA Sh.a.**  
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Tirana - ALBANIA

This leaflet was last revised in July 2015.

**PAY ATTENTION**, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.