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**APPROVED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S3**

# BIROIDA 5 mg tablets

**Carbimazole**

**Contains sugar: lactose anhydrous 70 mg per tablet**

**Read all of this leaflet carefully before you start taking BIROIDA**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIROIDA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**



## 1. What BIROIDA is and what it is used for

Carbimazole belongs to a group of medicines called anti-thyroid medicines. BIROIDA is used for people with an over-active thyroid gland (called hyperthyroidism).

- It works by reducing the amount of thyroid hormones made in your thyroid gland.

- It can be used on its own, or with other treatments for an over-active thyroid gland.
- It can also be used before part of the thyroid gland has been removed by surgery. It helps the thyroid gland work properly before the surgery.

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

**Do not take BIROIDA:**

- if you are allergic (hypersensitive) to carbimazole or any other ingredients of BIROIDA (listed in section 6).
- if you are allergic to thiamazole, methimazole or propylthiouracil (other thyroid medication).
- if you have a serious blood disorder.
- if you have a severe liver disorder.
- if you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.
- if you suffer from tracheal obstruction, a life-threatening emergency that requires immediate therapy, manifests itself by cough, wheezing, exertional dyspnoea, haemoptysis, and respiratory arrest.

**Warnings and precautions**

Take special care with BIROIDA:

- if you have bone marrow depression.
- if you suffer from low total amount of red blood cells (anaemia) or abnormal levels of platelets (thrombocytopenia).
- if you start having a sore throat, bruising or bleeding, mouth sores, fever and general weakness. You should immediately stop taking BIROIDA and seek medical advice immediately.
- if you have mild or moderate liver problems.

- if you are receiving radio-iodine (for thyroid problems).
- If you have swelling in your neck called an intrathoracic goitre.

BIROIDA can cause harm to an unborn baby. If you could get pregnant, use reliable contraception from the time you start treatment and during treatment.

Tell your doctor straight away if you develop fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis). BIROIDA may need to be discontinued.

Your doctor may ask you for occasional blood tests to help him determine how you are responding to treatment.

Radio-iodine is another treatment for hyperthyroidism. If you need radio-iodine treatment, your doctor will tell you to stop taking BIROIDA temporarily.

**Other medicines and BIROIDA**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

- Theophylline, used to treat asthma or breathing problems.
- Medicines called anticoagulants, which are used to thin the blood e.g. warfarin.
- Steroids such as prednisolone.
- An antibiotic called erythromycin.
- A medicine for heart failure called digoxin.
- Medicines for high blood pressure called beta-blockers.

**BIROIDA with, food, drink and alcohol**

BIROIDA may be taken with or without food.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

**Pregnancy**

BIROIDA can cause harm to an unborn baby.

If you could get pregnant, use reliable contraception from the time you start treatment and during treatment.

Your treatment with BIROIDA may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

**Breastfeeding**

Do not breastfeed if you are taking BIROIDA. This is because small amounts may pass into the mother's milk.

**Driving and using machines**

The effects of BIROIDA on the ability to drive and operate machinery have not been established. Do not drive or use machinery when you are on BIROIDA unless you are sure your judgement and co-ordination are not affected.

**BIROIDA contains lactose**

BIROIDA tablets contain lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BIROIDA.

## 3. How to take [PRODUT NAME]

Do not share medicines prescribed for you with any other person.

Always take BIROIDA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult and elderly dose is 10 mg to 60 mg daily according to the severity of the disorder. The dose should be gradually reduced to the smallest amount which will control the disease.

Your doctor will tell you how long your treatment with BIROIDA will last. If you have the impression that the effect of BIROIDA is too strong or too weak, tell your doctor or pharmacist.

**If you take more BIROIDA than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to take BIROIDA**

If you miss a dose of BIROIDA, take it as soon as possible. However if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking BIROIDA**

In order to maintain control of the thyroid gland, you may need to continue to take BIROIDA for several months. Your doctor will decide when treatment can be stopped.

## 4. Possible side effects

BIROIDA can have side effects.

Not all side effects reported for BIROIDA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIROIDA, please consult your

health care provider for advice.

If any of the following happens, stop taking BIROIDA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing,
- lung problems, with symptoms that include shortness of breath or a cough
- kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine,
- sore throat,
- mouth ulcers,
- high temperature or fever,
- significant tiredness,
- increased bruising or bleeding tendency,
- you are feeling generally unwell or think that you may have an infection,
- deadly skin disease (e.g. Stevens-Johnson Syndrome). Symptoms of these will include cough, aching, headaches, fever, red rash across the face and the trunk of the body.

These are all very serious side effects. If you have them, you may have had a serious reaction to BIROIDA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- muscle pain or weakness,
- yellowing of your skin or the whites of your eyes,
- nerve problems, with symptoms that include pain, pins-and-needles and numbness,
- swollen lymph nodes or swelling of the glands in your mouth,
- feeling faint (low blood sugar).

These could be signs of muscle problems, jaundice or inflammation of the liver and under medical supervision your doctor may want you to stop taking the medicine and carry out some blood tests on you. These are all serious side effects. You may need urgent medical attention.

BIROIDA can cause bone marrow depression which causes a reduction in the number of blood cells and reduces the ability to fight infection. If it is not treated as soon as it is detected the condition can become life-threatening. Your doctor should carry out tests to check for bone marrow depression before restarting your treatment.

Tell your doctor if you notice any of the following:

*Frequency unknown*

- feeling sick,
- headache,
- skin rashes, including urticaria (nettle rash),
- itching,
- stomach upset,
- painful joints,
- hair loss,
- loss of taste,
- inflammation of the pancreas (acute pancreatitis).

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

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s

publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BIROIDA.

## 5. How to store BIROIDA

Store all medicines out of reach of children.

- Store at or below 25 ºC. Protect from moisture.
- Keep in the original container until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What BIROIDA contains

Each uncoated tablet contains 5 mg of carbimazole.

Contains sugar: lactose anhydrous 70 mg per tablet.

The other ingredients are: croscarmellose sodium, lactose anhydrous and magnesium stearate.

### What BIROIDA looks like and contents of the pack

White coloured, round shaped, uncoated tablets, debossed “5” on one side and break line on other side.

Contents of the pack:

PVC/PE/PVDC/Aluminium foil blisters in brown coloured cartons of 20, 28, 30, 50, 56, 100 and 112 pack sizes. Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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**Registration number**

BIROIDA 54/21.3/0149

**Access to the corresponding Professional Information**

To follow