Applicant : Eurolab (Pty) Ltd
Proprietary name : Caloxa 50 mg
Dosage form and strength : Film-coated tablets, 50 mg
Date of submission : 13 October 2022
Approval date : 31 January 2023

APPROVED PATIENT INFORMATION LEAFLET FOR CALOXA

SCHEDULING STATUS: **S4**

Caloxa 50 mg

Bicalutamide

Contains lactose

Read all of this leaflet carefully before you start taking Caloxa 50 mg

- 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
- Caloxa 50 mg 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 Caloxa is and what it is used for
2. What you need to know before you take Caloxa
3. How to take Caloxa
4. Possible side effects
5. How to store Caloxa
6. Contents of the pack and other information

1. What Caloxa is and what it is used for

Bicalutamide belongs to a group of medicines called non-steroidal anti-androgen.

Bicalutamide works by interfering with the actions of male sex hormones (androgens). It is used for the treatment of advanced prostate cancer in combination with hormone therapy or after surgery.

Ask your doctor or healthcare professional if you have any questions about why Caloxa has been prescribed for you.

2. What you need to know before you take Caloxa

Do not take Caloxa

if you are hypersensitive (allergic) to bicalutamide or any of the other ingredients of Caloxa (listed in section 6).

If you are taking any other medicines, including those available without a prescription, herbal or complementary medicines.

Warnings and precautions

Special care should be taken with Caloxa:

- If you suffer from liver problems.

Other medicines and Caloxa

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

Tell your health care provider if you are taking any of the following medicines:

- Ketoconazole and cimetidine

- Warfarin

Driving and using machines

Caloxa can affect your ability to drive, do not drive or use machines until the effects of caloxa subsides.

Caloxa contains Lactose

Caloxa contains lactose monohydrate, which is a type of sugar.

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

3. How to take Caloxa

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

Always take Caloxa exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

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

The usual dose is one tablet each day.

Take your medication exactly as directed by your doctor.

Swallow your tablet whole with a drink of water.

Take this medicine at the same time each day to avoid missing any doses. If you do miss a dose, take it when you remember unless it is nearly time for your next dose. If your next dose is due, leave out the missed dose and take the next dose on time. Do not take two doses together.

Do not stop taking Caloxa without speaking with your doctor first.

This medicine is for you. Never give it to others even if their condition appears to be the same as yours.

Before taking any 'over-the-counter' medicines, check with your pharmacist which medicines are safe for you to take alongside Caloxa.

Keep your regular appointments with your doctor so your progress can be monitored. Caloxa can cause changes to certain blood tests that your doctor may want to check.

Before having any kind of surgery, including dental or emergency treatment, tell your surgeon, dentist or doctor that you are taking Caloxa.

If you take more Caloxa than you should

Never take more than the prescribed dose. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Where possible take the container with you, even if it is empty.

If you forget to take caloxa

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

4. Possible side effects

Caloxa can have side effects.

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

Important: If you experience serious breathlessness, chest infection, swelling of your mouth or face, chest pain, blood in your urine, or yellowing of the skin and whites of your eyes, then contact your doctor straight away or go to the accident and emergency department of your local hospital.

Side effects are:

- Feeling or being sick
- Diarrhoea

These are frequent side effects:

- anaemia
- lack of appetite (anorexia)
- depression
- reduced sex drive
- dizziness
- drowsiness
- sleeplessness
- heart attack
- high blood pressure
- hot flushes

- cough
- sore throat
- sneezing
- fever
- chills
- flu-like symptoms
- abdominal pain
- bloating
- indigestion
- constipation
- nausea
- changes in your liver
- itchy dry skin
- loss of hair
- sweating
- rash
- development of breasts in males
- breast tenderness
- sexual inability
- Weakness
- increased weight

These are less frequent side effects:

- allergic reactions

- nervousness
- confusion
- bleeding from the rectal passage
- vomiting
- liver failure

These side effects have been reported but the frequency is unknown:

- decreased number of white blood cells
- increased blood sugar levels
- increased frequency of urination at night

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 or nurse. 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 Caloxa.

5. How to store caloxa

Store at or below 25 °C. Store in original package.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton.

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

6. Contents of the pack and other information

What Caloxa contains

The active substance is Bicalutamide.

The other ingredients are:

- Lactose monohydrate
- Sodium starch glycolate
- Povidone K -30
- Purified water
- Magnesium stearate
- Hypromellose E 5
- Titanium dioxide
- Polyethylene glycol 400

What Caloxa looks like and contents of the pack

White to off-white, round, biconvex, film coated tablets debossed ‘B 50’ on one side and plain on other side.

Caloxa 50 mg Tablets: 10 tablets per Clear PVC / PVdC-Aluminium blister strips, supplied in a pack size of 30.

Holder of certificate of registration

Eurolab (Pty) Ltd.

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