

Prosmide®

Bicalutamide

Forms and presentation

Prosmide®50: Film coated tablets: Box of 30.

Composition

Prosmide®50: Each film coated tablet contains Bicalutamide 50mg.

Excipients: Lactose, Crospovidone, Povidone, Magnesium Stearate, Hypromellose, Titanium dioxide, Macrogol.

Why should you take Prosmide®?

Therapeutic class: Endocrine therapy.

ATC code: L02BB03

Prosmide® is prescribed for the treatment of prostate cancer alone or in combination with other medications. Prosmide® may also be used to treat other conditions determined by your physician. Prosmide® is a non steroidal anti-androgen. It works by blocking the action of testosterone.

What should you know about Prosmide®?

Prosmide® may cause dizziness, so do not drive or operate machinery until you know how your body responds to the medication.

What is the recommended dosage of Prosmide®?

ADULTS

For prostate cancer: one tablet once daily.

How is Prosmide® taken?

Take Prosmide® exactly as prescribed by your physician, at the same time each day. Prosmide® can be taken with or without food.

What to do if you miss a dose?

Take the forgotten dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and go back to your regular schedule. Do not take two doses at the same time.

What to do in case of over dosage?

In case you suspect an overdose, contact your physician immediately.

Are there any drug or food interactions with Prosmide®?

Prosmide® can be taken with most other drugs; however it is important to consult your physician before combining it with oral anticoagulants such as warfarin. Inform your physician if you are taking any other prescription or non prescription medications, herbal preparations, or dietary supplements.

Avoid co-administration of Prosmide® with alcohol as this may decrease your ability to drive or perform other hazardous tasks.

What are the side effects of Prosmide®?

Common side effects may include:

Anxiety, depression, sleeplessness, dizziness, weakness, back pain, bone pain, muscle weakness, nausea, indigestion, gases, pelvic pain, frequent urination, loss of bladder control, urinary retention, impotence, decreased

sexual ability, bronchitis, cough, sore throat, hot flashes, abnormal skin sensations, sweating, weight change.

Be sure to consult your physician if you experience any of the following severe side effects: severe allergic reactions (rash, difficulty in breathing, tightness in the chest, edema of the mouth, face, lips, and tongue), flu-like symptoms, difficulty in breathing, pneumonia, stomach pain, loss of appetite, nausea, vomiting, muscle aches, tenderness of the right upper quadrant, yellowing of the skin or eyes, dark urine, and chest pain.

Precautions about Prosmide®

Prosmide® must be used with caution in elderly patients. Prosmide® is not recommended for use in children since safety and efficacy have not been established. Consult your physician if you have any liver diseases prior to taking Prosmide®.

What are the cases in which you should not take Prosmide®?

Do not take Prosmide® if you are allergic to the drug or to any of its components.

What should you do if you are pregnant or breastfeeding?

Non steroidal anti-androgens are usually given to men. However, if one of these medicines is needed by a woman, it is very important that an effective method of avoiding pregnancy be used during treatment. Since non steroidal anti-androgens block the effect of the male hormone, testosterone, they may interfere with the normal development of a male fetus.

How to store Prosmide®?

Store below 30° C.

Keep in original pack in intact conditions.

Date of revision: February 2015.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Medicament: keep out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Benta S.A.L.
Dbayeh - Lebanon