

Patient package insert in accordance with the pharmacists' regulations

(preparations) - 1986)

Read this package insert carefully in its entirety before using this medicine:

The dispensing of this medicine requires a physician's prescription.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in December 2011.

# BICALUTAMIDE INOVAMED 150 mg

## Film-coated tablets

### Composition:

#### Active ingredient:

Each film-coated tablet contains: Bicalutamide 150 mg.

Each tablet contains also approximately 182 mg Lactose Monohydrate.

#### Inactive ingredients:

Lactose monohydrate, Povidone (K-29/32), Crospovidone, Sodium Lauryl Sulfate, Magnesium Stearate, Purified Water, Hypromellose, Titanium Dioxide (E171), Macrogol (PEG 4000).

#### Therapeutic group:

Anti-androgenic agent that interferes with some of the actions of androgens (male hormones) within the body.

#### Indication:

For treatment of prostate cancer.

### When should the preparation not be used?

Do not use this medicine if you have a sensitivity to any of its ingredients.

This medicine is not intended for women, including pregnant or breast-feeding women.

Do not give this medicine to children.

Do not use this medicine concomitantly with terfenadine, astemizole or cisapride.

### Do not use this medicine without consulting a physician before starting treatment:

If you suffer from malfunction of the liver. If you suffer from diabetes and you are taking "LHRH analogues" that include Goserelin, Buserelin, Leuprolin (Leuprolide) and Triptorelin.

#### Warnings:

During treatment with this medicine, periodic liver function tests should be considered. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

This preparation contains lactose (in the form of lactose monohydrate) and titanium dioxide that might cause allergy in patients sensitive to these ingredients.

### How will this medicine affect your daily life?

Use of this medicine may sometimes cause drowsiness, and therefore, caution should be exercised while driving, operating dangerous machinery or while engaging in any other activity requires alertness.

#### Drug interactions:

If you are taking another drug concomitantly, or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions, especially for medicines belonging to the following groups: oral anticoagulants, antihistamines (terfenadine or astemizole), cisapride (for some types of indigestion), cyclosporin (to suppress the immune system), calcium channel blockers (for the treatment of high blood pressure or some heart conditions), ketoconazole or cimetidine.

#### Side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, such as:

Very common (affecting more than 1 in 10 patients) side effects:

Dizziness, constipation, nausea, tender or enlarged breasts, hot flushes, feeling weak, swelling, anaemia (may cause paleness and fatigue).

Common (affecting less than 1 in 10 patients) side effects:

Yellowing of the skin or whitening of the eyes (jaundice). These may be indications of liver malfunction or in rare cases liver failure. Loss of appetite, decreased libido, depression, drowsiness, digestion problems, swelling, flatulence, hair loss, renewed hair growth or additional hair growth, itching, dry skin, skin rash, impotency, weight gain, chest pains, decrease in cardiac function, heart attack. The preparation may sometimes cause changes in the blood, which may require that your doctor perform certain blood tests.

#### Side effects that require special attention:

Very common (affecting more than 1 in 10 patients) side effects:

Abdomen pain, blood in the urine (very common): refer to the doctor immediately. Severe breathing difficulties, or sudden worsening of breathing difficulties, possibly accompanied by cough or fever. Some patients taking this medicine may develop an inflammation of the lungs called interstitial lung disease (uncommon): refer to the doctor immediately.

Common (affecting less than 1 in 10 patients) side effects:

Yellowing of the skin and the white part of the eye - these may be indications of liver malfunction or in rare cases liver failure: refer to the doctor immediately. Abdomen pain, blood in the urine: refer to the doctor immediately.

Uncommon side effects: Allergic reaction, the symptoms of which include a sudden beginning of: severe itching of the skin (with raised lumps) or swelling of the face, lips, tongue, throat or other parts of the body, shortness of breath, wheezing or breath difficulties - refer to the doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

#### Dosage:

According to doctor's instructions only.

If not otherwise instructed by the doctor, the usual dose for adults is one tablet daily.

Do not exceed the recommended dosage.

If you forget to take a dose at the specified time, do not take an extra dose, but continue with your usual dosing schedule.

#### Directions for use:

Do not crush, chew or divide the tablet! Swallow the tablet whole with water.

Take the tablet everyday at the same time.

#### How can you contribute to the success of the treatment?

Complete the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor.

#### Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place, out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a physician!

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm.

**Do not give this medicine to your relatives, neighbours or acquaintances.**

Do not take medicines in the dark! Check the label and dose each time you take your medicine. Wear glasses if you need them.

**Storage:** Store in a cool place (below 25°C) in the original pack. Even if stored as recommended, medicines may be kept for a limited period only. Notice the expiry date which is stated on the blister and carton. In case of doubt, consult the pharmacist who dispensed the medicine. Do not store different medications in the same package.

**Licence numbers:** 146-99-33443-00

**Manufacturer:** Synthon, The Netherlands (by Synthon Hispania, Spain, including the batch release).

**Registration Holder & Importer:** Novartis Ltd., P.O. Box 62, Even Yehuda 40500,

BCLTMD-INVMD-150-PIL-08/12