Applicant : Eurolab (Pty) Ltd
Proprietary name : Tasdiam 50 mg & 150 mg
Dosage form and strength : Film-coated tablets 50 mg & 150 mg
Date of submission : 01 June 2020
Approval date : 06 June 2020

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

Tasdiam 50 mg tablets

Tasdiam 150 mg tablets

Bicalutamide

Contains Lactose

- **Read all of this leaflet carefully before you start taking TASDIAM**
- 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.
- Tasdiam 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 **Tasdiam** is and what it is used for
2. What you need to know before you take **Tasdiam**
3. How to take **Tasdiam**
4. Possible side effects
5. How to store **Tasdiam**
6. Contents of the pack and other information

1. What TASDIAM is and what it is used for

Bicalutamide belongs to a group of medicines called hormone inhibitors. It blocks the undesired effect of the male sex hormones (androgens) and inhibits cell growth in the prostate this way. **Tasdiam** 50 is used for the treatment of locally advanced prostate cancer. It is taken together with a medicine known as luteinising hormone-releasing hormone (LHRH) analogue or with the surgical removal of the testicles.

Tasdiam 150 is used as the only agent for the management of patients with locally advanced, non-metastatic prostate cancer for whom surgical and medical castration is not appropriate.

2. What you need to know before you take TASDIAM

Do not take Tasdiam

- you are hypersensitive (allergic) to bicalutamide or any of the other ingredients of **Tasdiam** (listed in section 6).
- if you are breast-feeding.
- **Tasdiam** should not be taken by women or must not be given to children or adolescents.

Warnings and precautions

Take special care with Tasdiam:

- if you have liver function problems. If this is the case, your doctorwill regularly perform liver function tests.

- if your kidney function is severely impaired.
- if you suffer from heart disease your doctor should regularly monitor your heart function.

- if you have diabetes and are already taking an 'LHRH analogue'. These include goserelin, buserelin, leuprorelin and triptorelin

Other medicines and TASDIAM

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.) the use of **Tasdiam** with these medicines may cause undesirable interactions.

If you take **Tasdiam** with one of the following medicines, the level of **Tasdiam** in the blood may be increased, resulting in an increase in side-effects of **Tasdiam**:

- Cimetidine for treating stomach ulcers and
- Ketoconazole for treating fungal infections of the skin and nails.
- The following medicines should not be used together with Tasdiam: Astemizole, cisapride and ciclosporin.
- Tasdiam may increase the level of warfarin in the blood. For patients who are already receiving warfarin, the prothrombin time/INR should be closely monitored.

TASDIAM with food and drinking

Tasdiam can be taken before, during or after a meal, but you can also take them without food. Swallow the tablets with some water or another liquid. Do not chew the tablets.

Pregnancy and breastfeeding

Tasdiam is not to be taken by women and must not be given to breast-feeding mothers.

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.

Driving and using machines

Tasdiam can cause drowsiness and sleepiness (Somnolence), it is recommended that you do not drive or use machines until the effect subsides.

TASDIAM contains Lactose

Tasdiam contains lactose. If you have an intolerance to some sugars, such as lactose, contact your doctor immediately.

3. How to use TASDIAM

Do not share medicines prescribed for you with any other person.
Always take **Tasdiam** exactly as your doctor has instructed you has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet daily. It is better to take your tablet at the same time every day. If you have the impression that the effect of **Tasdiam** is too strong or too weak, talk to your doctor or pharmacist.

If you take more TASDIAM 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 possible, take the tablets or the box with you to show the doctor what you have taken

If you forget to take TASDIAM

If you forget to take **Tasdiam**, take your dose when you remember and then take your next dose at the usual time.

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

If you stop taking TASDIAM

Do not stop taking your tablets unless your doctor tells you.

4. Possible side effects

Tasdiam can have side effects.

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

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

Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching, fainting, yellowing of the skin and eyes, also called jaundice.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **Tasdiam**. You may need urgent medical attention or hospitalisation. All of these very serious side-effects are not frequently encountered.

The action of **Tasdiam** may cause certain expected side-effects. These include hot flushes, itchy skin, and in addition, breast tenderness and enlarged breast tissue, which may be reduced by concomitant castration. **Tasdiam** may also be associated with the concurrence

of diarrhoea, nausea, vomiting, weakness and dry skin. Severe liver changes may occur. The changes are frequently passing, clearing or improving despite continued therapy or following stopping of therapy. Periodic liver function testing should be done. Heart/vascular effects such as chest pain, heart failure, abnormal ECG tracing and irregular heart beat may occur. Reduction in blood platelets may occur.

In addition, the following side-effects were reported:

Infections and infestations

Less frequent: Lung and upper respiratory tract infections: bronchitis, pneumonia, sepsis.

Blood and the lymphatic system disorders

Less frequent: Anaemia.

Immune system disorders

Less frequent: Angioedema (swelling of the face, lips and mouth).

Endocrine disorders

Frequent: Hot flushes.

Metabolism and nutrition disorders

Frequent: Weight gain.

Less frequent: Large amounts of liquid in the tissue spaces, weight loss.

Has been reported, but frequency unknown: Diabetes, high blood sugar levels.

Psychiatric disorders

Less frequent: Reversible neurological reactions such as nervousness, inability to sleep, mental depression, confusion, dizziness.

Has been reported, but frequency unknown: Sleepiness.

Nervous system disorders

Less frequent: Chills, headache, drowsiness, reversible nervousness, sleeplessness, mental depression, confusion, dizziness.

Eye disorders

Less frequent: Visual disturbances including chromatopsia (imperfect perception of colour) and impaired adaptation or increased sensitivity to light.

Cardiac disorders

Less frequent: Chest pain, heart failure, change in normal heart beat and ECG (recording of the electrical activity of the heart) changes such as abnormal pattern.

Vascular disorders

Less frequent: High blood pressure.

Respiratory, thoracic and mediastinal disorders

Frequent: Runny nose, cough or hoarseness, fever, shortness of breath, breathlessness and tightness of chest or wheezing, sore throat, chest pain.

Gastro-intestinal disorders

Frequent: Diarrhoea, constipation, nausea.

Less frequent: Gastro-intestinal or rectal bleeding, dryness of mouth,

bloated feeling, windiness, indigestion, vomiting, loss of appetite.

Hepato-biliary disorders

Has been reported, but frequency unknown: Hepatitis or jaundice, cholestatic jaundice.

Skin and subcutaneous tissue disorders

Frequent: Itching, hair loss, dry skin.

Less frequent: Skin rash, rash, itching of skin, death of the outer skin layer.

Has been reported, but frequency unknown: Sweating, excessive hair growth.

Musculoskeletal, connective tissue and bone disorders

Less frequent: Muscle and joint weakness, muscle weakness in hands, arms, feet and legs.

Renal and urinary disorders

Less frequent: Blood in the urine.

Has been reported, but frequency unknown: Excessive need to urinate during the night.

Reproductive system and breast disorders:

Frequent: Development of breasts in males, decreased sex drive, sexual inability, breast tenderness, milky secretion from the breasts.

General disorders

Frequent: Unusual weakness.

Less frequent: Chills, headache, chest pain, fever, flu-like symptoms.

Has been reported, but frequency unknown: Abdominal pain, pain, pelvic pain.

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 **TASDIAM**.

5. How to store TASDIAM

Store at or below 25 ºC. Do not remove the blisters from the carton until required for use.

Keep all medicines out of the reach and sight of children.

Do not take the medicine after the expiry date on the container.

Return any 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 Tasdiam contains

The active substance is bicalutamide 50 mg or 150 mg.

The other ingredients are lactose monohydrate, magnesium stearate, Povidone K – 25, sodium starch glycolate and a film coating of Opadry OY-S-9622.

What TASDIAM looks like and contents of the pack

Tasdiam 50:

White, round, biconvex, film-coated tablets with a diameter of 6,5 mm.

Tasdiam 150:

White, round, scored, film-coated tablets with a diameter of 10,5 mm.

Cartons contain 28 or 30 film-coated tablets packed in PVC/PVDC/Aluminium foil blisters.

Each blister strip contains 10 or 14 tablets.

Holder of certificate of registration

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2144

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Tasdiam 150: 44/21.12/1023