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Sotamide® 250

Sobhan Oncology

Flutamide

Oral tablet

Read all of this leaflet carefully before you start taking this medicine.

- *Keep this leaflet. You may need to read it again.*
- *If you have further question, ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.*

In this leaflet:

1- What Sotamide® is and what it is used for

Sotamide® is used to treat:
Prostatic Carcinoma:
For use in combination with LHRH-agonists for the management of locally confined Stage B2-C metastatic carcinoma of the prostate.

2- Before you take Sotamide®

When you must not use Sotamide®?

Sotamide® is not to be administered to patients with a known hypersensitivity to the active substance Sotamide® or to another Ingredient of Sotamide®.
The following information tells you when to use Sotamide® only under certain condition or with special care. Please ask your doctor.
This information also applies, if you have experienced one of these conditions recently.
Due to reports that show Sotamide® can cause liver toxicity during treatment, the use of this drug in patients with a history of liver failure is not allowed.
This medicine contains Lactose, if you have intolerance to this ingredient; please consult your physician before taking the drug.

Usual pediatric dose:

Safety and efficacy of Sotamide® have not been established.

Usual geriatric dose:

Although the elimination half-life of Sotamide® and its active metabolite (hydroxyflutamide) are increased in the elderly, no adjustment of dosage on the basis of age is needed.

Use in pregnancy and breast feeding:

Sotamide® is a hormonal agent and is considered a potential teratogen. Follow safe handling procedures when preparing, administrating, or dispensing Sotamide®.
Futamide is for use only in men. This product has no indication for women, and should not be used in this population, particularly for nonserious or non-life-threatening conditions. (Category D).

Take special care with Sotamide®:

There have been post marketing reports of hospitalization and rarely death due to liver failure in patients taking Sotamide®. (Liver failure includes jaundice, encephalopathy and acute liver failure)
Long-term administration of Sotamide® in patients with hepatic impairment should be based on a careful evaluation of risk-benefit. Serum transaminase levels should be measured prior to starting treatment with Sotamide®. Sotamide® is not recommended in patients whose ALT values exceed twice the upper limit of normal. Serum transaminase level should then be measured monthly for the first 4 months of therapy, and periodically thereafter. Liver function tests also should be obtained at the first sign and suggestive of liver dysfunction (eg, nausea, vomiting, abnormal pain, fatigue, anorexia, "flu-like" symptoms, hyperbilirubinuria, jaundice, right upper quadrant tenderness). If at any time, a patient has jaundice, or their ALT level rise above 2 times the upper limit of normal, Sotamide® should be immediately discontinued with close follow-up of liver tests until resolution.
Regular assessment of serum prostate specific antigen (PSA) may be helpful in monitoring the patient's response. If PSA levels rise significantly and consistently during Sotamide® therapy, the patient should be evaluated for clinical progression. For patients who have objective progression of disease together with an elevated PSA, a treatment period free of antiandrogen while continuing the LHRH analog may be considered. Caution also recommended in conditions predisposing to Aniline toxicity.

Drug Interactions

If you received other drugs; even such as OTC drugs, please tell your physician or pharmacist. The following drug interactions and/ or related problems have been selected on the basis of their potential clinical significance.
Anticoagulants:
Increases in prothrombin time have been noted in patients receiving long-term Warfarin therapy after Sotamide® was initiated. Therefore close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when Sotamide® are administrated concomitantly with Warfarin.

3- How to take Sotamide®

Patient receiving Sotamide® should be under the supervision of a physician. Instruction of usage of drug and duration of medication should be decided by physician, based on the type, severity, and progression of disease. The usual dosage of Sotamide® is 250 mg, three times a day (750mg/ day). The tablets are to be taken whole with some liquid, preferably after the meals.

Overdose:

A single dose that would result in potentially life-threatening symptoms has not been established. Doses as high as 1500mg per day, given for up to 36 weeks in clinical trials, caused gynaecomastia, breast tenderness, and increased hepatic enzyme concentration, all of which have been reported with usual adult dose.
There is no specific antidote to overdose with Sotamide®. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is recommended, with treatment of observed symptoms as warranted.
Inform your doctor if you suspect that you have exceeded the dose. If you missed a dose or taken too small a dose of Sotamide®, the next time you take your medication, take the normal dose and return to your usual dosing schedule.

4- Possible side effects

Every medicine has some side effects or risks associated with their use. Although most people take medicines without experiencing any side effects, some may be affected. In these cases, please consult your physician or pharmacist. Please inform your doctor or pharmacist, if you experience any side effects not mentioned in this leaflet. The following side/adverse effects have been selected on the basis of their potential clinical significance:

Those indicating need for medical attention:

Incidence less frequent:
Anemia (unusual tiredness or weakness); Edema (swelling of face, fingers, feet, or lower legs); Leukopenia (cough or hoarseness, fever or chills, lower back or side pain, painful or difficult urination); Neuromuscular symptoms or neuropathy (numbness, tingling, pain, or muscle weakness in hands, arms, feet, or legs); and Skin rash.
Incidence rare:
Hepatitis or jaundice, including cholestatic jaundice (dark urine, "flu-like" symptoms, gastrointestinal upset, loss of appetite, nausea or vomiting, pain or tenderness in upper right area of abdomen, unusual tiredness, yellow eyes or skin); Hypertension; Skin itching; Mental depression; Pulmonary disorder (chest pain, cough, shortness of breath, weak and fast heartbeat); and Thrombocytopenia (black, tarry stools, blood in urine or stools, pinpoint red spots on skin, unusual bleeding or bruising).

Those indicating need for medical attention only if they continue or are bothersome:

Incidence more frequent:
Nausea; Diarrhea; and Impotence or decrease in sexual desire.
Incidence less frequent:
Vomiting; Decrease or loss of appetite; and Gynaecomastia.
Incidence rare:
Confusion; Dizziness; Headache; Nervousness; Trouble in sleeping; and Weakness.

Those not indicating need for medical attention:

Incidence more frequent:
Hot flush (feeling of warmth, flushing, sudden sweating)

5- Storing Sotamide®

Keep out of the reach and sight of children.
Store in the original package in order to protect from light.
Store Sotamide® below 30 C.
Do not use Sotamide® after the expiry date which is stated on the carton after "Exp.'.

6- Further Information

What Sotamide® contains
Medicinally active substance:
1 tablet contains 250 mg Sotamide®.
Other ingredient:
Microcrystalline cellulose; Maize starch; Lactose monohydrate; Sodium dodecylsulphate; Colloidal anhydrous silica; and Magnesium stearate.

Contains of the pack

Original pack of 84 tablets.

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SOBT-0250-LF-02

Sobhan Oncology Co.		
Leaflet	*Flutamide (Sotamide® 250)*	
Color	PANTONE 288U	PANTONE 185U
Size	240 mm x 220 mm	Tolerance: ±1mm
File name	SOBT-0250-LF-02	
Date	03.09.1399	