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Lenasob®

Sobhan Oncology

Lenalidomide

Capsule; Oral: 5mg, 10mg, 15mg, 25mg

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 use it in same condition or pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1- What Lenasob® is and what it is used for
2- Before you take Lenasob®
3- How to take Lenasob®
4- Possible side effects
5- Storing Lenasob®
6- Further information

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

Antiangiogenesis agent; Immunomodulator.

Lenasob® is used to treat:

Multiple myeloma:

In combination with dexamethasone for the treatment of multiple myeloma patients who have received at least 1 prior therapy.

Myelodysplastic syndromes:

For the treatment of patients with transfusional dependent anemia because of low - or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

2-Before you take Lenasob®

When you must not use Lenasob®?

Lenasob® is not to be administered to patients with a known hypersensitivity to the active substance Lenasob® or to another ingredient of Lenasob®.

Usual pediatric dose:

Safety and efficacy of Lenasob® in patients below the age of 18 years have not established.

Usual geriatric dose:

Appropriate studies performed to date have not demonstrate geriatrics specific problems that would limit the usefulness of Lenasob® in the elderly. Howevere, elderly patients are more likely to have age releted renal function impairment, which may require care in dosing selection and monitoring of renal function.

Use in pregnancy:

Lenasob® is contraindicated in females who are or may become pregnant and who are not using the two required types of birth control or who are not continually abstaining from intercourse. If pregnancy does occur during treatment, Lenasob® should be discontinued immediately and the patient should be reffered to an obstetrician / gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Adequate and well controlled studies in humans have shown than a similar drug, thalidomide causes serious and life threatening adverse effects in the fetus (Category X).

Use in breast feeding:

Its not known whether Lenasob® is distributed into human milk. Because many drugs are distributed in human milk and because of the potential: adverse effects in nursing infants, a decision should be made whether to discontinue nursing or to discontinue Lenasob®, taking into account the importance of the drug to the mother.

Take special care with Lenasob®:

The following may be especially important in patient monitoring

Complete blood counts, including:

- Hematocrit and
- Platelet count and
- White blood cell counts with differential

(Monitor weekly for the first 8 weeks and at least mounthly there aftar for cytopenias; associations with significant neutropenia and thrombocytopenia).

Pregnancy testing:

(Weekly during the first 4 weeks of therapy and every 4 weeks thereafter in women with regular menstrual cycles; Every 2 weeks in women with irregular menstrual cycles).

Renal function impairment:

Because Lenasob® is primarily excreted unchanged by the kidney, adjustments to the starting dose of Lenasob® are recommended to provide appropriate drug exposure in patients with moderate or severe renal impairment or in patients on dialysis.

Drug interactions

Digoxin:

When digoxin was coadministered with Lenasob®, Lenasob® may increase peak plasma concentrations of digoxin.

Erythropoietins or other drugs that increase the risk of thrombosis should be used with caution in patients taking Lenasob®.

Coadministration with food does not alter the extent of absorption.

How to take Lenasob®

Usual adult dose:

Multiple myeloma:

Oral, 25mg daily administered as a single 25mg capsule on days 1 through 21 of repeated 28 day cycles.

Myelodysplastic syndromes:

Oral, 10mg daily on days 1 through 21.

Overdose:

There is no specific antidote to overdose with Lenasob®. Treatment is generally symptomatic and supportive.

3- Possible side effects

Those indicating need for medical attention:

Incidence more frequent:

Dyspnea (shortness of breath; difficult or labored breathing; tightness in chest; wheezing); febrile neutropenia (black, tarry stools; chills; cough, fever; lower back or side pain; painful or difficult urination; pale skin; sore throat; ulcer, sores or white spots in mouth; unusual bleeding ;unusual tiredness or weakness); hypokalemia (convulsion; decrease urine, dry mouth; irregular heartbeat; increased thirst; loss of appetite; mood changes; muscle pain or cramps; nausea or vomiting; numbness or tingling in hands), leukopenia (black, tarry stools; chest painful or difficult urination; shortness of breath; ulcers, or white spots on lips or in mouth; swellen glands; unusual bleeding, unusual tiredness or weakness); thrombocytopenia (black, tarry stools; bleeding gums; blood in urine or stools; pinpoint red spots on skin; unusual bleeding or bruising).

Incidence rare:

Deep venous thrombosis (pain, redness or swelling in arm or leg) pulmonary embolism (anxiety; chest pain; caugh; fainting, fast heart beat; sudden shortness of breath or troubled breathing; dizziness).

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

Incidence more frequent:

Abdominal pain (stomach pain); anemia (pale skin, troubled breathing with exertion; unusual bleeding or bruising unusual tiredness or weakness); anorexia; arthralgia (pain in joints; muscle pain or stiffness; difficulty in moving); back pain; bronchitis (cough producing mucus; difficulty breathing; tightness in chest; wheezing); cellulitis (itching, pain, redness, swelling, tenderness, warmth on skin); chest pain; contusion (hemorrhage beneath unbroken skin); depression (discouragement; feeling sad or empty; irritability; lack of appetite; loss of interest or pleasure; tiredness; trouble concentrating; trouble sleeping); diarrhea, mild, dizziness; dry mouth: dry skin, dysgeusia (loss of taste, change of taste); dysuria (difficult or painful urination; burning while urinating); ecchymosed (bruising; large, flat, blue or purplish patches in the skin), edema (swelling); edema peripheral (swelling of hands, ankles, feet or lower legs); epistaxis (bloody nose), erythema (flushing, redness of skin, unusually warm skin), fatigue; headache; hypertension (blurred vision; dizziness; nervousness; pounding in the ears; slow or fast heartbeat), hypoesthesia (abnormal or decreased touch sensation); hypomagnesaemia (drowsiness; loss of appetite, mood or mental changes; muscle spasms; itching; seizures, nausea; vomiting; trembling; unusual tiredness or weakness) hypothyroidism, insomnia; myalgia (joint pain, swellen joints; muscle aching or cramping; muscle pains or stiffness; difficulty in moving); nasopharyngitis (stuffy or runny nose; muscle aches); nausea; night sweats; pain; pain in limb (pain in arms or legs) palpitations (fast, irriegular, pounding, or racing, heartbeat or pulse); peripheral neuropathy (burning, numbness, tingling or painful sensations; weakness in arms, hands, legs or feet; unsteadiness or awkwardness); pharyngitis (body aches or pain; congestion; cough; dryness or soreness of troat, fever; hoarseness; runny nose; tender, swollen glands in neck; trouble in swelling; voice changes).

4- Storing Lenasob®:

Store below 30°C. Protect from light and moisture. Keep out of reach and sight of children.

5- Further information

What Lenasob® contains

Medicinally active substance:

1 capsule contains 5,10,15, 25 mg Lenalidomide.

Other ingredient:

Microcrystalline cellulose; Lactose Anhydrous; Croscarmellose sodium and Magnesium stearate.

Auxiliary labeling

Patients should take the capsules daily with water and should not break, chew or open.

Contains of the pack:

Each bottle contains 21 capsules.

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