דצמבר 2025

רופא /ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשירים:

לנלידומיד טבע 2.5 מ"ג, 5 מ"ג, 7. 5 מ"ג 10 מ"ג, 15 מ"ג, 20 מ"ג, 25 מ"ג, כמוסות קשיחות
Lenalidomide Teva 2.5 mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg Hard capsules

Contains:
Each hard capsule contains 2.5 mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg Lenalidomide (as hydrochloride hydrate)

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Multiple Myeloma (MM):
Lenalidomide Teva is indicated for the treatment of multiple myeloma.

Myelodysplastic Syndromes:
Lenalidomide Teva is indicated for patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
Lenalidomide Teva 7.5 mg is not indicated for treatment in MDS.

Mantle Cell Lymphoma:
Lenalidomide Teva is indicated for the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma (MCL).

Follicular Lymphoma:
Lenalidomide Teva in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated follicular lymphoma.

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

עדכונים בעלון לרופא

4.4 Special warnings and precautions for use

Pregnancy warning
Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys' malformations similar to those described with thalidomide (see sections 4.6 and 5.3). If lenalidomide is taken during pregnancy, a

teratogenic effect of lenalidomide in humans is expected.

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For male patients taking lenalidomide, pharmacokinetic data has demonstrated that lenalidomide is present in human semen at extremely low levels during treatment and is undetectable in human semen 3 days after stopping the substance in the healthy subject (see section 5.2). As a precaution and taking into account special populations with prolonged elimination time such as renal impairment, all male patients taking lenalidomide must meet the following conditions:

- Understand the expected teratogenic risk if engaged in sexual activity with a pregnant woman or a woman of childbearing potential.
- Understand that Lenalidomide is present in human semen during treatment. As a precaution, all male patients taking Lenalidomide, including those who have had a vasectomy as seminal fluid may still contain Lenalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption and for at least 4 weeks after cessation of treatment if their partner is pregnant or of child bearing potential and has no contraception.
- Understand which are the effective contraceptive methods that his female partner can use.
- He should not donate blood, semen or sperm during treatment (including during dose interruptions) and for at least 4 weeks following discontinuation of Lenalidomide.
- If his partner becomes pregnant whilst he is taking Lenalidomide or 4 weeks after he has stopped taking Lenalidomide he should inform his treating physician immediately. The partner should inform her physician immediately. It is recommended that she is referred to a physician specialised in teratology for evaluation and advice.
- He should never share Lenalidomide Teva with anyone else, and he should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- The maximum duration of a prescription is 12 weeks.

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~~*Male Patients:*~~

~~Clinical data has demonstrated the presence of lenalidomide in human semen. Therefore, males receiving Lenalidomide Teva must always use a latex/ polyurethane condom during any sexual contact with females of childbearing potential, even if they have undergone a successful vasectomy. In the case of a male patient with an allergy to latex or polyurethane, at least one highly effective form of contraception should be used by any female sexual partner.~~

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Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking lenalidomide in combination therapy, and to a lesser extent in patients with multiplemyeloma, myelodysplastic syndromes and mantle cell lymphoma taking lenalidomide monotherapy, combined oral contraceptive pills are not recommended (see also section 4.5). If a patient is currently using combined oral contraception the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4−6 weeks after discontinuing combined oral

contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone (see section 4.5).

Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia.

Copper-releasing intrauterine devices are generally not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with neutropenia or thrombocytopenia.

Pregnancy testing
For women of childbearing potential a pregnancy test must be performed prior to the dispending of each prescription of Lenalidomide Teva.

- A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.
- According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential.
- The test results should be from a date no earlier than 3 days prior to issuing the prescription and ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.
- Dispensing of Lenalidomide Teva to women of childbearing potential should occur within 7 days of the prescription.

Prior to starting treatment
A medically supervised pregnancy test should be performed during the consultation, when Lenalidomide Teva is prescribed, or in the 3 days prior to the visit to the prescriber, once the patient had been using 2 effective contraception methods for at least 4 weeks (contraception is needed unless the patient commits to absolute and continuous sexual abstinence confirmed on monthly basis). The test should ensure the patient is not pregnant when she starts treatment with Lenalidomide Teva.

Follow-up and end of treatment
A medically supervised pregnancy test should be repeated every 4 weeks, including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation. These pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.