אוקטובר 2024

רופא /ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון לרופא ובעלון לצרכן 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 ובעלון לצרכן

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 ועלון לצרכן עודכנו, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

עדכונים בעלון לרופא

4.2 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Women who are pregnant.
- Women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met (see sections 4.4 and4.6).

Females of childbearing potential may be treated with lenalidomide provided adequate

precautions are taken to avoid pregnancy.

If hormonal or IUD contraception is medically contraindicated, two other effective or highly effective methods may be used.

Females of childbearing potential being treated with Lenalidomide Teva must have pregnancy testing (sensitivity of at least 25 mIU/mL). The test should be performed prior to beginning therapy within 3 days prior to prescribing Lenalidomide Teva and then monthly thereafter (including dose interruptions). **Pregnancy testing should be performed also 4 weeks following discontinuation of Lenalidomide Teva therapy.**

Pregnancy testing and counseling must be performed if a patient misses her period or if there is any abnormality in menstrual bleeding. If pregnancy occurs, Lenalidomide Teva must be immediately discontinued. Under these conditions, the patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling.

4.3 Special warnings and precautions for use

When Lenalidomide Teva is given in combination with other medicinal products, the corresponding Summary of Product Characteristics must be consulted prior to initiation of treatment.

Embryo-Fetal Toxicity

If lenalidomide is used during pregnancy, it may cause birth defects or death to a developing baby. Females of childbearing potential must be advised to avoid pregnancy while on Lenalidomide Teva. Two reliable forms of contraception should be used simultaneously during therapy, during dose interruptions and for at least 4 weeks following discontinuation of therapy. There are no adequate and well-controlled studies in pregnant females.

Lenalidomide Teva can be prescribed only in agreement with RMP limitations.

Reproductive Risk and Special Prescribing Requirements (Lenalidomide Teva RMP-PPP)

Revlimid can be prescribed and dispensed only if following the Lenalidomide Teva Risk Management Program. All patients must follow the Lenalidomide Teva Risk Minimization Program in order to receive Lenalidomide Teva (refer to black box warning section).

Female Patients:

Two effective contraception methods must be used by female patients of childbearing potential for at least 4 weeks prior to beginning of treatment, throughout treatment duration, during treatment interruptions and at least 4 weeks after discontinuation unless continuous abstinence from heterosexual sexual contact is the chosen method. Reliable contraception is indicated even where there has been a history of infertility. Females of childbearing potential should be referred to a qualified provider of contraceptive methods, if needed.

Criteria for women of non-childbearing potential

A female patient or a female partner of a male patient is considered to have childbearing potential unless she meets at least one of the following criteria:

- Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year (Amenorrhoea following cancer therapy or during breast-feeding does not rule out childbearing potential).
- Premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis.

Counselling

For women of childbearing potential, lenalidomide is contraindicated unless all of the following are met:

- She was explained the expected teratogenic risk to the unborn child
- She was explained the need for effective contraception, without interruption, 4 weeks before starting treatment, throughout the entire duration of treatment, and 4 weeks after the end of treatment
- Even if a woman of childbearing potential has amenorrhea she must follow all the advice on effective contraception
- She should be capable of complying with effective contraceptive measures
- She is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy
- She was explained that once established on contraception for 4 weeks the patient is required to have a medically supervised negative pregnancy test. The first prescription for Lenalidomide can only be given after one negative medically supervised pregnancy test
- She was explained the need to commence the treatment as soon as Lenalidomide is dispensed following a negative pregnancy test
- She was explained the need and accepts to undergo pregnancy testing every 4 weeks except in case of confirmed tubal sterilisation
- She acknowledges that she was explained the hazards and necessary precautions associated with the use of Lenalidomide
- If she becomes pregnant whilst taking Lenalidomide, she should stop therapy and inform her treating physician immediately. It is recommended to refer the partner to a physician specialised or experienced in teratology for evaluation and advice

Cessation of menses due to anti-cancer therapy, do not exclude the potential to become pregnant.

Two reliable forms of contraception must be used simultaneously unless continuous abstinence from heterosexual sexual contact is the chosen method.

Contraception methods for a female of childbearing potential:

Highly effective contraceptive methods:

- Intrauterine device (IUD)
- Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
- Tubal ligation
- Partner's vasectomy

Additional effective barrier methods:

- Condom
- Diaphragm
- Cervical cap

Contraceptive methods must include:
At least 1 highly effective method AND 1 additional effective barrier method.

Pregnancy testing
Females of childbearing potential must have a negative pregnancy test (sensitivity of at least 25 mIU/mL) before starting the therapy, and then monthly thereafter (including dose interruptions and including 4 weeks following discontinuation of Lenalidomide therapy). The test should be performed within 3 days prior to prescribing Lenalidomide Teva. A prescription for Lenalidomide Teva for a female of childbearing potential must not be issued by the prescriber until a negative pregnancy test has been verified by the prescriber.

Pregnancy testing and counseling should be performed if a patient misses her period or if there is any abnormality in her pregnancy test or in her menstrual bleeding. Lenalidomide Teva therapy must be discontinued during this evaluation.

Pregnancy test results should be verified by the prescriber prior to dispensing **any** prescription.

If pregnancy does occur during treatment, Lenalidomide Teva must be discontinued immediately.

Any suspected fetal exposure to Lenalidomide Teva must be reported to the attending physician and Teva. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Do not breastfeed during therapy (including dose interruptions).

Patients should not donate blood while taking Lenalidomide Teva, during any breaks (discontinuations) in your therapy, and for 4 weeks following discontinuation of Lenalidomide Teva therapy.

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.

Contraception should be started in this partner at least 4 weeks prior to the start of a sexual relationship with the patient and continued throughout Lenalidomide therapy including dose interruptions and for 4 weeks following discontinuation of therapy.

Patients should not donate blood and semen or sperm during treatment (including during dose

interruptions) and for at least 4 weeks following discontinuation of Lenalidomide Teva therapy.

Once treatment has started and during dose interruptions, pregnancy testing for females of childbearing potential should be performed every 4 weeks.

Pregnancy testing should be performed also 4 weeks following discontinuation of Lenalidomide Teva therapy.

[…]

4.6 Fertility, pregnancy and lactation

[…]

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 should use condoms throughout treatment duration, during dose interruption and for ~~1 week~~ at least 4 weeks after cessation of treatment if their partner is pregnant or of childbearing potential and has no contraception.

[…]

עדכונים בעלון לצרכן

2. לפני שימוש בתרופה

[…]

תרומת דם

אין לתרום דם במהלך הטיפול בלנלידומיד טבע, במהלך הפסקות בטיפול, וכן במהלך 4 שבועות ~~ולפחות 7~~ ~~ימים~~ לאחר סיום הטיפול.

תרומת זרע

אין לתרום זרע במהלך הטיפול בלנלידומיד טבע, במהלך הפסקות בטיפול, וכן במהלך 4 שבועות לאחר סיום הטיפול.

[…]

מידע עבור נשים הנוטלות לנלידומיד טבע

- אין להשתמש בלנלידומיד טבע אם את בהיריון, כיוון שהתרופה צפויה לפגוע בעובר.
- אל תיכנסי להיריון במהלך הטיפול בלנלידומיד טבע. על-כן אם את אישה בגיל הפוריות, את חייבת לנקוט באמצעים יעילים למניעת היריון (ראי סעיף "מניעת היריון").
- אם הרית במהלך הטיפול בלנלידומיד טבע, עלייך להפסיק את הטיפול ולהודיע לרופא מייד.
- יש להמתין 4 שבועות נוספים לאחר סיום השימוש בתרופה לפני שמנסים להיכנס להיריון.

[…]

מניעת היריון

מידע עבור נשים הנוטלות לנלידומיד טבע

לפני תחילת הטיפול בתכשיר, שאלי את הרופא אודות יכולתך להיכנס להיריון, גם במקרה בו את חושבת שהסיכוי שתוכלי להיכנס להיריון נמוך.

אם את יכולה להיכנס להיריון:

- עלייך לעבור בדיקות היריון תחת פיקוחו של הרופא (לפני כל טיפול, לפחות פעם בארבעה שבועות במהלך הטיפול, במהלך הפסקות בטיפול ולפחות 4 שבועות לאחר סיום הטיפול), למעט במקרה בו

ביצעת הליך אשר מונע מעבר של הביציות דרך החצוצרות אל עבר הרחם (tubal sterilisation).

בנוסף -

- יש להשתמש ב-2 שיטות יעילות למניעת היריון בו-זמנית בכל פעם, לפחות במשך 4 שבועות לפני תחילת הטיפול, במהלך הטיפול, במהלך הפסקות בטיפול ובמשך לפחות 4 שבועות לאחר סיום הטיפול – אלא אם התנזרות מפעילות מינית עם גבר היא השיטה הנבחרת.
  הרופא ייעץ לך לגבי אמצעי מניעה מתאימים.

מידע עבור גברים הנוטלים לנלידומיד טבע

לנלידומיד עובר לנוזל הזרע. אם בת זוגך בהיריון או יכולה להיכנס להיריון, והיא לא משתמשת בשיטות יעילות למניעת היריון, אתה חייב להשתמש בקונדום במהלך הטיפול, ולפחות 4 שבועות ~~7 ימים~~ לאחר סיום הטיפול, אפילו אם עברת ניתוח לשם עיקור (וזקטומיה).

אם לא ניתן להשתמש בקונדום, יש לוודא כי בת הזוג משתמשת באמצעי למניעת היריון יעיל אחד לפחות במשך 4 שבועות לפני תחילת הטיפול, במהלך הטיפול, במהלך הפסקות בטיפול ובמשך 4 שבועות לאחר סיום הטיפול.

אין לתרום זרע במהלך הטיפול בלנלידומיד טבע, במהלך הפסקות בטיפול ובמהלך 4 שבועות ~~7 ימים~~ לאחר סיום הטיפול.

העלון לצרכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות http://www.health.gov.il וניתן לקבלו מודפס ע"י פניה לחברת טבע.