נובמבר 2020

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

שלום רב,

הנדון : **<u>עדכוני בטיחות בעלוני התכשיר</u>**
Jakavi 5/10/15/20 mg
ג'קאבי 5/10/15/20 מ"ג

חברת נוברטיס ישראל בע"מ מבקשת להודיע על עדכון בעלונים לרופא ולצרכן של התכשירים **Jakavi 5/10/15/20 mg**.

העדכון הינו הוספת התוויה לתכשיר, טיפול ב GvHD כמפורט מטה בצבע אדום:

התוויות התכשיר:

<u>Myelofibrosis (MF)</u>

Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

<u>Polycythaemia vera (PV)</u>

Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.

<u>Graft versus host disease (GvHD)</u>

Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

חומר פעיל:

Ruxolitinib (as phosphate) 5/10/15/20 mg

בהודעה זו מפורטים העדכונים המהווים עדכון הנוגע להתוויה שהוספה ולמידע בטיחותי בלבד. למידע מלא יש לעיין בעלוני התכשיר.
העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על-ידי פניה לבעל הרישום:
נוברטיס ישראל בע"מ.
תוצרת הארץ 6, ת.ד. 7126, תל אביב

<u>העדכונים מסומנים בצבע כחול עם קו תחתי.</u>

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העדכונים בעלון לרופא:
עודכן בנובמבר 2022, להלן העדכונים העיקריים הקשורים לתוספת ההתוויה בעלונים:

4.1 Therapeutic indications

Myelofibrosis (MF)

Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

Polycythaemia vera (PV)

Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.

Graft versus host disease (GvHD)

Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

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4.2 Posology and method of administration

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The recommended starting dose of Jakavi in acute and chronic graft versus host disease (GvHD) is 10 mg given orally twice daily. Jakavi can be added to the continued use of corticosteroids and/or calcineurin inhibitors (CNIs).

Dose modifications

Graft versus host disease
Dose reductions and temporary interruptions of treatment may be needed in GvHD-patients with thrombocytopenia, neutropenia, or elevated total bilirubin after standard supportive therapy including growth-factors, anti-infective therapies and transfusions. One dose level reduction step is recommended (10 mg twice daily to 5 mg twice daily or 5 mg twice daily to 5 mg once daily). In patients who are unable to tolerate Jakavi at a dose of 5 mg once daily, treatment should be interrupted. Detailed dosing recommendations are provided in Table 3.

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Table 3 Dosing recommendations during ruxolitinib therapy for GvHD patients with thrombocytopenia, neutropenia or elevated total bilirubin

Laboratory parameter	Dosing recommendation
Platelet count <20,000/mm^3	Reduce Jakavi by one dose level. If platelet count ≥20,000/mm^3 within seven days, dose may be increased to initial dose level, otherwise maintain reduced dose.
Platelet count <15,000/mm^3	Hold Jakavi until platelet count ≥20,000/mm^3, then resume at one lower dose level.
Absolute neutrophil count (ANC) ≥500/mm^3 to <750/mm^3	Reduce Jakavi by one dose level. Resume at initial dose level if ANC >1,000/mm^3.
Absolute neutrophil count <500/mm^3	Hold Jakavi until ANC >500/mm^3, then resume at one lower dose level. If ANC >1,000/mm^3, dosing may resume at initial dose level.
Total bilirubin elevation not caused by GvHD (no liver GvHD)	>3.0 to 5.0 x upper limit of normal (ULN): Continue Jakavi at one lower dose level until ≤3.0 x ULN.
	>5.0 to 10.0 x ULN: Hold Jakavi up to 14 days until total bilirubin ≤3.0 x ULN. If total bilirubin ≤3.0 x ULN dosing may resume at current dose. If not ≤3.0 x ULN after 14 days, resume at one lower dose level.
	>10.0 x ULN: Hold Jakavi until total bilirubin ≤3.0 x ULN, then resume at one lower dose level.
Total bilirubin elevation caused by GvHD (liver GvHD)	>3.0 x ULN: Continue Jakavi at one lower dose level until total bilirubin ≤3.0 x ULN.

Special populations

Renal impairment

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There are no data for GvHD patients with ESRD.

Hepatic impairment

In MF patients with any hepatic impairment the recommended starting dose based on platelet count should be reduced by approximately 50% to be administered twice daily. Subsequent doses should be adjusted based on careful monitoring of safety and efficacy. The recommended starting dose is 5 mg twice daily for PV patients. Patients diagnosed with hepatic impairment while receiving ruxolitinib should have complete blood counts, including a white blood cell count differential, monitored at least every one to two weeks for the first 6 weeks after initiation of therapy with ruxolitinib and as clinically indicated thereafter once their liver function and blood counts have been stabilised. Ruxolitinib dose can be titrated to reduce the risk of cytopenia.

In patients with mild, moderate or severe hepatic impairment not related to GvHD, the starting dose of ruxolitinib should be reduced by 50% (see section 5.2).

In patients with GvHD liver involvement and an increase of total bilirubin to >3 x ULN, blood counts should be monitored more frequently for toxicity and a dose reduction by one dose level is recommended.

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Paediatric population
The safety and efficacy of Jakavi in children and adolescents aged up to 18 years with MF and PV have not been established. No data are available (see section 5.1).

In paediatric patients (12 years of age and older) with GvHD, the safety and efficacy of Jakavi are supported by evidence from the randomised phase 3 studies REACH2 and REACH3. The Jakavi dose in paediatric patients with GvHD aged 12 years and older is the same as in adults. The safety and efficacy of Jakavi have not been established in patients less than 12 years of age.

Treatment discontinuation
Treatment of MF and PV may be continued as long as the benefit-risk remains positive. However the treatment should be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms since initiation of therapy.

It is recommended that, for patients who have demonstrated some degree of clinical improvement, ruxolitinib therapy be discontinued if they sustain an increase in their spleen length of 40% compared with baseline size (roughly equivalent to a 25% increase in spleen volume) and no longer have tangible improvement in disease-related symptoms.

In GvHD, tapering of Jakavi may be considered in patients with a response and after having discontinued corticosteroids. A 50% dose reduction of Jakavi every two months is recommended. If signs or symptoms of GvHD reoccur during or after the taper of Jakavi, re-escalation of treatment should be considered.

4.4 Special warnings and precautions for use

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Special populations

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Hepatic impairment
The starting dose of Jakavi should be reduced by approximately 50% in MF and PV patients with hepatic impairment. Further dose modifications should be based on the safety and efficacy of the medicinal product. In GvHD patients with hepatic impairment not related to GvHD, the starting dose of Jakavi should be reduced by approximately 50% (see sections 4.2 and 5.2).

4.8 Undesirable effects
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Acute GvHD
The most frequently reported overall adverse drug reactions were thrombocytopenia, anaemia and neutropenia.

Haematological laboratory abnormalities identified as adverse drug reactions included thrombocytopenia (85.2%), anaemia (75.0%) and neutropenia (65.1%). Grade 3 anaemia was reported in 47.7% of patients (grade 4 not applicable per CTCAE v4.03). Grade 3 and 4 thrombocytopenia were reported in 31.3% and 47.7% of patients, respectively.

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The three most frequent non-haematological adverse drug reactions were cytomegalovirus (CMV) infection (32.3%), sepsis (25.4%) and urinary tract infections (17.9%).

The three most frequent non-haematological laboratory abnormalities identified as adverse drug reactions were increased alanine aminotransferase (54.9%), increased aspartate aminotransferase (52.3%) and hypercholesterolaemia (49.2%). The majority were of grade 1 and 2.

Discontinuation due to adverse events, regardless of causality, was observed in 29.4% of patients.

Chronic GvHD
The most frequently reported overall adverse drug reactions were anaemia, hypercholesterolemia and increased aspartate aminotransferase.

Haematological laboratory abnormalities identified as adverse drug reactions included anaemia (68.6%), thrombocytopenia (34.4%) and neutropenia (36.2%). Grade 3 anaemia was reported in 14.8% of patients (grade 4 not applicable per CTCAE v4.03). Grade 3 and 4 neutropenia were reported in 9.5% and 6.7% of patients, respectively.

The three most frequent non-haematological adverse drug reactions were hypertension (15.0%), headache (10.2%) and urinary tract infections (9.3%).

The three most frequent non-haematological laboratory abnormalities identified as adverse drug reactions were hypercholesterolaemia (52.3%), increased aspartate aminotransferase (52.2%) and increased alanine aminotransferase (43.1%). The majority were grade 1 and 2.

Discontinuation due to adverse events, regardless of causality, was observed in 18.1% of patients.

Tabulated list of adverse drug reactions from clinical studies
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The safety of Jakavi in acute GvHD patients was evaluated in the phase 3 study REACH2, including data from patients initially randomised to Jakavi (n=152) and patients who received Jakavi after crossing over from the best available therapy (BAT) arm (n=49). The median exposure upon which the adverse drug reaction frequency categories were based was 8.9 weeks (range 0.3 to 66.1 weeks).

The safety of Jakavi in chronic GvHD patients was evaluated in the phase 3 study REACH3, including data from patients initially randomised to Jakavi (n=165) and patients who received Jakavi after crossing over from BAT (n=61). The median exposure upon which the adverse drug reaction frequency categories were based was 41.4 weeks (range 0.7 to 127.3 weeks).

In the clinical study programme the severity of adverse drug reactions was assessed based on the CTCAE, defining grade 1=mild, grade 2=moderate, grade 3=severe, grade 4=life-threatening or disabling, grade 5=death.

Adverse drug reactions from clinical studies in MF and PV (Table 4) and in acute and chronic GvHD

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(Table 5) are listed by MedDRA system organ class. **.....**

Table 5 Frequency category of adverse drug reactions reported in the phase 3 studies in GvHD

	Acute GvHD (REACH2)	Chronic GvHD (REACH3)
Adverse drug reaction	**Frequency category**	**Frequency category**
Infections and infestations		
CMV infections	Very common	Common
CTCAE[3] grade ≥3	Very common	Common
Sepsis	Very common	-
CTCAE grade ≥3	Very common	-
Urinary tract infections	Very common	Common
CTCAE grade ≥3	Common	Common
BK virus infections	-	Common
CTCAE grade ≥3	-	Uncommon
Blood and lymphatic system disorders		
Thrombocytopenia[1]	Very common	Very common
CTCAE grade 3	Very common	Common
CTCAE grade 4	Very common	Very common
Anaemia[1]	Very common	Very common
CTCAE grade 3	Very common	Very common
Neutropenia[1]	Very common	Very common
CTCAE grade 3	Very common	Common
CTCAE grade 4	Very common	Common
Pancytopenia[1,2]	Very common	-
Metabolism and nutrition disorders		
Hypercholesterolaemia[1]	Very common	Very common
CTCAE grade 3	Common	Common
CTCAE grade 4	Common	Uncommon
Weight gain	-	Common
CTCAE grade ≥3	-	N/A[5]
Nervous system disorders		
Headache	Common	Very common
CTCAE grade ≥3	Uncommon	Common
Vascular disorders		
Hypertension	Very common	Very common
CTCAE grade ≥3	Common	Common

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Gastrointestinal disorders		
Increased lipase[1]	-	Very common
CTCAE grade 3	-	Common
CTCAE grade 4	-	Uncommon
Increased amylase[1]	-	Very common
CTCAE grade 3	-	Common
CTCAE grade 4	-	Common
Nausea	Very common	-
CTCAE grade ≥3	Uncommon	-
Constipation	-	Common
CTCAE grade ≥3	-	N/A[5]
Hepatobiliary disorders		
Increased alanine aminotransferase[1]	Very common	Very common
CTCAE grade 3	Very common	Common
CTCAE grade 4	Common	Uncommon
Increased aspartate aminotransferase[1]	Very common	Very common
CTCAE grade 3	Common	Common
CTCAE grade 4	N/A[5]	Uncommon
Musculoskeletal and connective tissue disorders		
Increased blood creatine phosphokinase[1]	-	Very common
CTCAE grade 3	-	Common
CTCAE grade 4	-	Common
Renal and urinary disorders		
Increased blood creatinine[1]	-	Very common
CTCAE grade 3	-	Common
CTCAE grade 4	-	N/A[5]

[1] Frequency is based on new or worsened laboratory abnormalities compared to baseline.
[2] Pancytopenia is defined as haemoglobin level <100 g/l, platelet count <100 x 10^9/l, and neutrophil count <1.5 x 10^9/l (or low white blood cell count of grade 2 if neutrophil count is missing), simultaneously in the same laboratory assessment.
[3] CTCAE Version 4.03.
[4] Grade ≥3 sepsis includes 20 (10%) grade 5 events.
[5] Not applicable: no cases reported

Description of selected adverse drug reactions

Anaemia

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In the phase 3 acute and chronic GvHD studies, anaemia CTCAE grade 3 was reported in 47.7% and 14.8% of patients, respectively.

Thrombocytopenia

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In the phase 3 acute GvHD study, grade 3 and 4 thrombocytopenia was observed in 31.3% and 47.7% of patients, respectively. In the phase 3 chronic GvHD study, grade 3 and 4 thrombocytopenia was lower (5.9% and 10.7%) than in acute GvHD.

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Bleeding

In the phase 3 acute GvHD study, grade 3 and 4 neutropenia was observed in 17.9% and 20.6% of patients, respectively. In the phase 3 chronic GvHD study grade 3 and 4 neutropenia was lower (9.5% and 6.7%) than in acute GvHD.

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In the comparative period of the phase 3 acute GvHD study, bleeding events were reported in 25.0% and 22.0% of patients in the ruxolitinib and BAT arms respectively. The sub-groups of bleeding events were generally similar between treatment arms: bruising events (5.9% in ruxolitinib vs. 6.7% in BAT arm), gastrointestinal events (9.2% vs. 6.7%) and other haemorrhage events (13.2% vs. 10.7%). Intracranial bleeding events were reported in 0.7% of patients in the BAT arm and in no patients in the ruxolitinib arm.

In the comparative period of the phase 3 chronic GvHD study, bleeding events were reported in 11.5% and 14.6% of patients in the ruxolitinib and BAT arms respectively. The sub-groups of bleeding events were generally similar between treatment arms: bruising events (4.2% in ruxolitinib vs. 2.5% in BAT arm), gastrointestinal events (1.2% vs. 3.2%) and other haemorrhage events (6.7% vs. 10.1%). No intracranial bleeding events were reported in either treatment arm.

Infections

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In the phase 3 acute GvHD study, during the *comparative period*, urinary tract infections were reported in 9.9% (grade ≥3, 3.3%) of patients in the ruxolitinib arm compared to 10.7% (grade ≥3, 6.0%) in the BAT arm. CMV infections were reported in 28.3% (grade ≥3, 9.3%) of patients in the ruxolitinib arm compared to 24.0% (grade ≥3, 10.0%) in the BAT arm. Sepsis events were reported in 12.5% (grade ≥3, 11.1%) of patients in the ruxolitinib arm compared to 8.7% (grade ≥3, 6.0%) in the BAT arm. BK virus infection was reported only in the ruxolitinib arm in 3 patients with one grade 3 event. During *extended follow-up* of patients treated with ruxolitinib, urinary tract infections were reported in 17.9% (grade ≥3, 6.5%) of patients and CMV infections were reported in 32.3% (grade ≥3, 11.4%) of patients. CMV infection with organ involvement was seen in very few patients; CMV colitis, CMV enteritis and CMV gastrointestinal infection of any grade were reported in four, two and one patients, respectively. Sepsis events, including septic shock, of any grade were reported in 25.4% (grade ≥3, 21.9%) of patients.
In the phase 3 chronic GvHD study, during the *comparative period*, urinary tract infections were reported in 8.5% (grade ≥3, 1.2%) of patients in the ruxolitinib arm compared to 6.3% (grade ≥3, 1.3%) in the BAT arm. BK virus infection was reported in 5.5% (grade ≥3, 0.6%) of patients in the ruxolitinib arm compared to 1.3% in the BAT arm. CMV infections were reported in 9.1% (grade ≥3, 1.8%) of patients in the ruxolitinib arm compared to 10.8% (grade ≥3, 1.9%) in the BAT arm. Sepsis events were reported in 2.4% (grade ≥3, 2.4%) of patients in the ruxolitinib arm compared to 6.3% (grade ≥3, 5.7%) in the BAT arm. During *extended follow-up* of patients treated with ruxolitinib, urinary tract infections and BK virus infections were reported in 9.3% (grade ≥3, 1.3%) and 4.9% (grade ≥3, 0.4%) of patients, respectively. CMV infections and sepsis events were reported in 8.8% (grade ≥3, 1.3%) and 3.5% (grade ≥3, 3.5%) of patients, respectively.

Elevated lipase

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In the *comparative period* of the phase 3 acute GvHD study, new or worsened lipase values were reported in 19.7% of patients in the ruxolitinib arm compared to 12.5% in the BAT arm; corresponding grade 3 (3.1% vs

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5.1%) and grade 4 (0% vs 0.8%) increases were similar. During *extended follow-up* of patients treated with ruxolitinib, increased lipase values were reported in 32.2% of patients; grade 3 and 4 were reported in 8.7% and 2.2% of patients respectively.

In the *comparative period* of the phase 3 chronic GvHD study, new or worsened lipase values were reported in 32.1% of patients in the ruxolitinib arm compared to 23.5% in the BAT arm; corresponding grade 3 (10.6% vs 6.2%) and grade 4 (0.6% vs 0%) increases were similar. During *extended follow-up* of patients treated with ruxolitinib, increased lipase values were reported in 35.9% of patients; grade 3 and 4 were observed in 9.5% and 0.4% of patients, respectively.

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Paediatric patients
A total of 20 patients aged 12 to <18 years with GvHD were analysed for safety: 9 patients (5 in the ruxolitinib arm and 4 in the BAT arm) in the study REACH2 and 11 patients (4 in the ruxolitinib arm and 7 in the BAT arm) in the study REACH3. Based on the similar exposure observed in adolescents and adults, the safety of ruxolitinib at the recommended dose of 10 mg twice daily is similar in frequency and severity.

Elderly
A total of 29 patients in study REACH2 and 25 patients in REACH3 aged >65 years and treated with ruxolitinib were analysed for safety. Overall, no new safety concerns were identified and the safety profile in patients >65 years old is generally consistent with that of patients aged 18-65 years old.

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העדכונים בעלון לצרכן:
עודכן בנובמבר 2022, להלן העדכונים העיקריים הקשורים לתוספת ההתוויה בעלונים:

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1. למה מיועדת התרופה?
ג'קאבי משמשת לטיפול ב:

- חולים מבוגרים עם טחול מוגדל או עם תסמינים הקשורים למיאלופיברוזיס, סוג נדיר של סרטן הדם.
- חולים מבוגרים עם פוליציטמיה ורה אשר עמידים או פיתחו חוסר סבילות להידרוקסיאוראה (hydroxyurea).
- חולים מבוגרים וילדים מגיל 12 ומעלה עם תסמונת השתל כנגד המאכסן (GvHD- graft versus host disease) בצורה חריפה/אקוטית או כרונית, בעלי תגובה לא מספקת לקורטיקוסטאורידים או טיפולים סיסטמים אחרים.

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תסמונת השתל כנגד המאכסן (GvHD) הינה סיבוך שמתרחש לאחר השתלה כאשר תאים ספציפיים (תאי T) בשתל התורם (כגון מח העצם) לא מזהים את התאים/האיברים של המאכסן, ותוקפים אותם. על ידי חסימה סלקטיבית של אנזימים הנקראים JAK (JAK1 ו-JAK2) ג'קאבי מפחיתה תסמינים וסימנים של המחלה (בצורתה הכרונית והאקוטית) ומובילה לשיפור במחלה ובשרידות התאים המושתלים.
קיימות שתי צורות של GvHD:
GvHD חריף/אקוטי- בדרך כלל מתפתח בשלב מוקדם, זמן קצר לאחר ההשתלה, ועלול לפגוע בעור, כבד ומערכת העיכול;
GvHD כרוני – אשר מתפתח מאוחר יותר, בדרך כלל שבועות או חודשים לאחר ההשתלה. כמעט כל איבר יכול להיות מושפע מ-GvHD כרוני.

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2.לפני השימוש בתרופה

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ילדים ומתבגרים

תרופה זו אינה מיועדת לילדים או מתבגרים מתחת לגיל 18 הסובלים ממיאלופיברוזיס או מפוליציטמיה ורה מכיוון שהשימוש של ג'קאבי בקבוצת גיל זו לא נחקר.

לטיפול בתסמונת השתל כנגד המאכסן (GvHD) ניתן להשתמש בג'קאבי בילדים מגיל 12 ומעלה.

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3. כיצד תשתמש בתרופה?

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המינון ההתחלתי המומלץ בפוליציטמיה ורה ותסמונת השתל כנגד המאכסן (GvHD) הינו 10 מ"ג פעמיים ביום.

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גם אם חל שיפור במצב בריאותך, אין להפסיק את הטיפול בתרופה ללא התייעצות עם הרופא. אם אתה מפסיק את הטיפול עם ג'קאבי התסמינים הקשורים במחלת המיאלופיברוזיס או במחלת פוליציטמיה ורה עלולים לחזור. בתסמונת הכשל כנגד המאכסן (GvHD) הפחתה במינון או הפסקת טיפול בג'קאבי אפשריים אם יש תגובה לטיפול ובפיקוח של הרופא שלך על התהליך. לכן, אין להפסיק נטילת ג'קאבי או לשנות את המינון בלי לדון בכך עם הרופא.

4. תופעות לוואי

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תסמונת השתל כנגד המאכסן (GvHD)

חלק מתופעות הלוואי עלולות להיות חמורות. פנה לסיוע רפואי מיידי לפני לקיחת המנה הבאה של התרופה אם אתה חווה את אחת מתופעות הלוואי החמורות הבאות:

תופעות לוואי שכיחות מאוד (very common) - תופעות העלולות להופיע ביותר מ-1 מתוך 10 מטופלים:

- חום, כאב, אדמומיות, ו/או קשיי נשימה (תסמינים אפשריים של זיהום בציטומגלווירוס cytomegalovirus (infection))
- חום, כאבים בעת מתן שתן (תסמינים אפשריים של זיהום בדרכי השתן)
- קצב לב מהיר, חום, בלבול ונשימה מהירה (תסמינים אפשריים לספסיס, מצב חמור שנוצר כתגובה לזיהום הגורם לדלקת נרחבת)
- עייפות, תשישות, עור חיוור (תסמינים אפשריים של אנמיה הנגרמת מרמות נמוכות של תאי דם אדומים), זיהומים תכופים, חום, צמרמורות, גרון כואב או כיבים בפה בעקבות זיהום (תסמינים אפשריים של נויטרופניה הנגרמת מרמות נמוכות של תאי דם לבנים), דימומים ספונטניים או חבורות (תסמינים אפשריים לטרומבוציטופניה הנגרמת מרמות נמוכות של טסיות דם)
- ירידה במספר כל שלושת הסוגים של תאי דם – תאי דם אדומים, לבנים וטסיות (pancytopenia)

תופעות לוואי נוספות

תופעות לוואי נוספות כוללות את התופעות הרשומות מטה. אם אתה חווה תופעות אלו פנה לרופא שלך או לרוקח.

תופעות לוואי שכיחות מאוד (very common) - תופעות העלולות להופיע ביותר מ-1 מתוך 10 מטופלים:

Novartis Israel Ltd.
P.O.Box 7126 6 Tozeret Haaretz street, Tel Aviv
Tel: 972-3-9201111 Fax: 972-3-9229331

נוברטיס ישראל בע"מ.
תוצרת הארץ 6, ת.ד. 7126, תל אביב
טלפון: 03-9201111 פקס: 03-922-9331

- רמות גבוהות של כולסטרול (hypercholesterolaemia)
- כאבי ראש
- לחץ דם גבוה
- רמות גבוהות של ליפאז בדם
- תוצאות בדיקות דם לא תקינות, היכולות להעיד על פגיעה אפשרית בלבלב (עמילאז מוגבר)
- בחילה
- תוצאות לא תקינות של תפקודי כבד
- עליה ברמות אנזימי שרירים בדם, העלולה להעיד על נזק לשרירים ו/או התפרקות שרירים (עליה ברמות קראטינין פוספוקינאז בדם)
- עליה ברמות קראטינין בדם, אשר בדרך כלל מתפנה על ידי הכליות אל השתן, אשר עלולה להעיד על כך שהכליות לא מתפקדות כראוי

תופעות לוואי שכיחות (common) - תופעות העלולות להופיע בעד 1 מתוך 10 מטופלים:

- חום, כאבים, אודם ו/או קושי בנשימה (תסמינים אפשריים לזיהום בוירוס BK)
- עליה במשקל
- עצירות

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בברכה,

יעל לוי טל
רוקחת ממונה

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