J-C Health Care Ltd.

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מאי 2024

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: **Balversa 3mg, 4mg & 5mg**

חברת ג'יי סי הלת'קר בע"מ (J-C Health Care Ltd.) מבקשת להודיעכם כי העלון לרופא של התכשירים הבאים התעדכן ב-04/2024. אין עדכונים בעלון לצרכן:
Balversa 3mg Film Coated Tablets, erdafitinib 3mg 165-77-36132-00
Balversa 4mg Film Coated Tablets, erdafitinib 3mg 165-78-36133-00
Balversa 5mg Film Coated Tablets, erdafitinib 3mg 165-79-36134-00

ההתוויות העדכניות המאושרות לתכשירים בישראל:
BALVERSA is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC), that has:
- Susceptible FGFR3 or FGFR2 genetiic alterations, and
- Progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

מרכיב פעיל:
erdafitinib

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug.

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס של באמצעות פנייה לבעל הרישום: יאנסן ישראל בע"מ , קיבוץ שפיים, 6099000, טל': 09-9591111.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן כטקסט ~~עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב), אך קיימים עדכונים נוספים.

בברכה,
דנית ראובני

רוקחת ממונה
ג'יי סי הלת'קר בע"מ

העדכונים העיקריים בעלון לרופא הינם:

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8.1 Clinical Trials Experience

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Table 1: Adverse Reactions Reported in ≥ 10% (Any Grade) or ≥5% (Grade 3-4) of Patients

Adverse Reaction	BALVERSA 8 mg daily (N=87)	
	All Grades (%)	Grade 3-4 (%)
Any	100	67
Gastrointestinal disorders	92	24
Stomatitis	56	9
Diarrhea	47	2
Dry mouth	45	0
Constipation	28	1
Abdominal pain[a]	23	2
Nausea	21	1
Vomiting	13	2
Metabolism and nutrition disorders	90	16
Decreased appetite	38	0
Hyponatremia	11	10
General disorders and admin. site conditions	69	13
Fatigue[b]	54	10
Pyrexia	14	1
Skin and subcutaneous disorders	75	16
~~Onycholysis~~[c] Nail disorder[c]	45	10
Dry skin[d]	34	0
Palmar-plantar erythrodysesthesia	26	6
Alopecia	26	0
Nail discoloration	11	0
Eye disorders	62	11
Dry eye[e]	28	6
Vision blurred	17	0
Lacrimation increased	10	0
Nervous system disorders	57	5
Dysgeusia	37	1
Infections and infestations	56	20
Paronychia	17	3
Urinary tract infection	17	6
Conjunctivitis	11	0
Respiratory, thoracic and mediastinal disorders	40	7
Oropharyngeal pain	11	1
Dyspnea[f]	10	2
Renal and urinary tract disorders	38	10
Hematuria	11	2
Musculoskeletal and connective tissue disorders	31	0
Musculoskeletal pain[g]	20	0
Arthralgia	11	0
Investigations	44	5
Weight decreased[h]	16	0
Blood creatinine increased	11	0

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12.3 Pharmacokinetics

Drug Interaction Studies
Clinical Studies

Effect of Other Drugs on erdafitinib

Moderate CYP2C9 Inhibitors:
Erdafitinib mean ratios (90% CI) for C_{max} and AUC_{inf} were 121% (99.9, 147) and 148% (120, 182), respectively, when co-administered with fluconazole, a moderate CYP2C9 and CYP3A4 inhibitor, relative to erdafitinib alone.

Strong CYP3A4 Inhibitors:
Erdafitinib mean ratios (90% CI) for C_{max} and AUC_{inf} were 105% (86.7, 127) and 134% (109, 164), respectively, when co-administered with itraconazole (a strong CYP3A4 inhibitor and P-gp inhibitor) relative to erdafitinib alone.

CYP3A4/2C9 Inducers:
Mean ratios (90% CI) of C_{max} and AUC_{inf} for free erdafitinib were 78% (72.76, 83.12) and 45% (39.74, 51.59), respectively, when co-administered with carbamazepine (a strong CYP3A4 and weak CYP2C9 inducer) relative to erdafitinib alone *[see Interactions (7.1)]*.

Effect of Erdafitinib on Other Drugs

CYP3A4 Substrates:

Mean ratios (90% CI) of C_{max} and AUC_{inf} for midazolam (a sensitive CYP3A4 substrate) were 86.29% (73.52, 101.28) and 82.11% (70.83, 95.18), respectively, when co-administered with erdafitinib relative to midazolam alone. Erdafitinib does not have a clinically meaningful effect on midazolam PK.

OCT2 Substrates:

Mean ratios (90% CI) of C_{max} and AUC_{inf} for metformin (a sensitive OCT2 substrate) were 108.66% (90.31, 130.75) and 113.92% (93.22, 139.23), respectively, when co-administered with erdafitinib relative to metformin alone. Erdafitinib does not have a clinically meaningful effect on metformin PK.

אין עדכונים בעלון לצרכן.