J-C Health Care Ltd.

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Johnson&Johnson

יוני 2025

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון: **טאלווי™ 2 מ"ג/מ"ל Talvey® 2mg/ml**
טאלווי™ 40 מ"ג/מ"ל Talvey® 40mg/ml

בעל הרישום J-C Health Care Ltd. מבקש להודיעכם כי העלונים לרופא ולצרכן של התכשירים שבנדון עודכנו ביוני 2025.

פרטי העדכון העיקריים מופיעים בהמשך *(טקסט שנוסף מסומן ב*אדום*, טקסט שהושמט מסומן כטקסט כחול עם קו חוצה)*, אך קיימים עדכונים נוספים.

מרכיב פעיל: Talquetamab 2mg/ml
Talquetamab 40mg/ml

ההתוויות המאושרות לתכשיר בישראל:

TALVEY is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti CD38 antibody and have demonstrated disease progression on the last therapy.

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

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום: J-C Health Care Ltd , קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,
שרון כץ
רוקחת ממונה

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בהודעה זו כלולים העדכונים המהותיים בלבד.

<u>עלון לצרכן</u>

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4. <u>תופעות לוואי</u>

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תופעות לוואי שכיחות - תופעות שמופיעות בעד משתמש אחד מתוך 10:

- נשירת שיער
- דימום, אשר עלול להיות חמור (דמם)
- זיהום בריאות (דלקת ריאות)
- זיהום נגיפי
- אלח דם (ספסיס)
- מספר נמוך של תאי דם לבנים מסוג נויטרופילים, המלווה בחום
- אדמומיות, נפיחות, עקצוץ או תחושת צריבה עם היסדקות של העור בכפות ידיים ו/או בכפות רגליים (תסמונת הידיים והרגליים (hand-foot syndrome))

<u>עלון לרופא</u>

4.4 Special warnings and precautions for use

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<u>Skin reactions</u>

TALVEY can cause skin reactions including rash, ~~maculo-papular rash,~~ erythema, ~~erythematous rash,~~ palmar-plantar erythrodysesthesia syndrome, as well as nail disorders (see section 4.8). Skin reactions including rash progression should be monitored for early intervention and treatment with corticosteroids. For Grade 3 or higher, or worsening Grade 1 or 2 rashes, oral steroids should also be administered. For non-rash skin reactions dose modification may be considered (see Table 6).
For skin reactions and nail disorders, TALVEY should be withheld based on severity and institutional guidelines should be followed (see section 4.2).

4.8 Undesirable effects

<u>Summary of the safety profile</u>

The most frequent adverse reactions were CRS (77%), dysgeusia (72%), hypogammaglobulinaemia (67%), nail disorder (56%), musculoskeletal pain (48%), anaemia (47%), ~~skin disorder (43%),~~ fatigue (43%), weight decreased (40%), skin disorder (37%), rash (39%), dry mouth (36%), neutropenia (35%), pyrexia (33%), xerosis (32%), thrombocytopenia (30%), upper respiratory tract infection (29%),

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lymphopenia (27%), dysphagia (24%), diarrhoea (25%), pruritus (23%), cough (23%), pain (22%), decreased appetite (22%) and headache (20%).

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Table 7: Adverse reactions in patients with multiple myeloma treated with TALVEY in MonumenTAL-1 (N=339)

System Organ Class Adverse Reaction	**Frequency category**	**Any Grade (%)**	**Grade 3 or 4 (%)**
Infections and infestations			
Bacterial infection*	Very common	40 (12%)	11 (3.2%)
Fungal infection*	Very common	39 (12%)	1 (0.3%)
COVID-19*#	Very common	63 (19%)	10 (2.9%)
Upper respiratory tract infection*	Very common	98 (29%)	7 (2.1%)
Sepsis*#	Common	15 (4.4%)	14 (4.1%)
Pneumonia*	Common	23 (7%)	11 (3.2%)
Viral infection*	Common	23 (7%)	6 (1.8%)
Blood and lymphatic system disorders			
Neutropenia*	Very common	119 (35%)	103 (30%)
Anaemia*	Very common	158 (47%)	99 (29%)
Thrombocytopenia	Very common	101 (30%)	71 (21%)
Lymphopenia	Very common	91 (27%)	83 (25%)
Leukopenia	Very common	62 (18%)	38 (11%)
Haemorrhage[1]	Common	27 (8%)	5 (1.5%)
Febrile neutropenia	Common	7 (2.1%)	7 (2.1%)
Immune system disorders			
Cytokine release syndrome	Very common	260 (77%)	5 (1.5%)
Hypogammaglobulinaemia[2]	Very common	227 (67%)	0
Metabolism and nutrition disorders			
Decreased appetite	Very common	76 (22%)	4 (1.2%)
Hypokalaemia	Very common	55 (16%)	12 (3.5%)
Hypophosphataemia*	Very common	49 (15%)	21 (6%)
Hypomagnesaemia	Very common	35 (11%)	0
Nervous system disorders			
Immune effector cell-associated neurotoxicity syndrome*	Very common	26 (10%)	6 (2.3%)
Encephalopathy[3]	Very common	36 (11%)	0
Headache*	Very common	69 (20%)	2 (0.6%)
Motor dysfunction[4]	Very common	38 (11%)	2 (0.6%)
Dizziness*	Very common	42 (12%)	8 (2.4%)
Sensory neuropathy[5]	Very common	34 (10%)	0
Respiratory, thoracic and mediastinal disorders			
Cough*	Very common	78 (23%)	0
Dyspnoea[6#]	Very common	39 (12%)	5 (1.5%)
~~Oral pain*~~	~~Very common~~	~~42 (12%)~~	~~0~~
Gastrointestinal disorders			
Dysgeusia‡[7]	Very common	245 (72%)	0
Dry mouth‡	Very common	122 (36%)	0
Dysphagia	Very common	82 (24%)	3 (0.9%)
Diarrhoea	Very common	84 (25%)	4 (1.2%)
Stomatitis[8]	Very common	67 (20%)	4 (1.2%)
Nausea	Very common	64 (19%)	0
Constipation	Very common	61 (18%)	0
Oral pain*	Very common	42 (12%)	0

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Abdominal pain*	Very common	35 (10%)	1 (0.3%)
Vomiting	Very common	34 (10%)	2 (0.6%)
Skin and subcutaneous tissue disorders			
Rash*	Very common	132 (39%)	12 (3.5%)
Skin disorder*	Very common	~~145 (43%)~~ 124 (37%)	0
Xerosis[9]	Very common	109 (32%)	0
Pruritus	Very common	79 (23%)	1 (0.3%)
Nail disorder*	Very common	191 (56%)	0
Palmar-plantar erythrodysesthesia syndrome	Common	31 (9%)	0
Alopecia	Common	30 (9%)	0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain*	Very common	164 (48%)	12 (3.5%)
General disorders and administrate site conditions			
Fatigue*	Very common	147 (43%)	12 (3.5%)
Weight decreased	Very common	134 (40%)	11 (3.2%)
Pyrexia*	Very common	113 (33%)	6 (1.8%)
Pain*	Very common	76 (22%)	7 (2.1%)
Oedema[10]	Very common	59 (17%)	0
Injection site reaction[11]	Very common	45 (13%)	0
Chills	Very common	39 (12%)	1 (0.3%)
Investigations			
Fibrinogen decreased	Very common	52 (15%)	12 (3.5%)
aPTT prolonged	Very common	49 (15%)	0
Transaminase elevation[12]	Very common	48 (14%)	12 (3.5%)
INR increased	Very common	47 (14%)	1 (0.3%)
Gamma-glutamyltransferase increased	Very common	36 (11%)	16 (4.7%)

Adverse reactions are coded using MedDRA Version 24.0.

‡ Per CTCAE v4.03, maximum toxicity grade for dysgeusia is 2 and maximum toxicity grade for dry mouth is 3.

* Grouped term

\# Contains fatal outcome(s)

1 Haemorrhage includes: Conjunctival haemorrhage, Epistaxis, Haematoma, Haematuria, Lower gastrointestinal haemorrhage, Periorbital haemorrhage, Petechiae, Rectal haemorrhage, Subdural haematoma and Vaginal haemorrhage.

2 Hypogammaglobulinaemia includes: hypogammaglobulinaemia and/or subjects with laboratory IgG levels below 500 mg/dL following treatment with talquetamab.

3 Encephalopathy includes: agitation, amnesia, aphasia, bradyphrenia, confusional state, delirium, disorientation, encephalopathy, hallucination, lethargy, memory impairment, restlessness, sleep disorder and somnolence.

4 Motor dysfunction includes: dysgraphia, dysphonia, gait disturbance, muscle spasms, muscular weakness and tremor.

5 Sensory neuropathy includes: dysaesthesia, hypoaesthesia, hypoaesthesia oral, neuralgia, peripheral sensory neuropathy, sciatica and vestibular neuronitis.

6 Dyspnoea includes: acute respiratory failure, dyspnoea, dyspnoea exertional, respiratory failure and tachypnoea.

7 Dysgeusia includes: ageusia, dysgeusia, hypogeusia and taste disorder.

8 Stomatitis includes: cheilitis, glossitis, glossodynia, mouth ulceration, oral discomfort, oral mucosal erythema, oral pain, stomatitis, swollen tongue, tongue discomfort, tongue erythema, tongue oedema and tongue ulceration.

9 Xerosis includes: dry eye, dry skin and xerosis.

10 Oedema includes: fluid retention, gingival swelling, hypervolaemia, joint swelling, lip swelling, oedema, oedema peripheral, periorbital oedema, peripheral swelling and swelling.

11 Injection site reaction includes: injection site discomfort, injection site erythema, injection site haemorrhage, injection site inflammation, injection site irritation, injection site plaque, injection site pruritus, injection site rash and injection site reaction.

12 Transaminase elevation includes: alanine aminotransferase increased, aspartate aminotransferase increased, and transaminases increased.