J-C Health Care Ltd.

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Johnson&Johnson

נובמבר 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 בנובמבר 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.

עלון לצרכן

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2. לפני השימוש בתרופה

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מידע חשוב על חלק מהמרכיבים של התרופה

טאלווי מכיל נתרן
טאלווי מכיל פחות מ-1 מילימול (23 מ"ג) נתרן, כלומר הוא למעשה "נטול נתרן".

טאלווי מכיל פוליסורבט 20 (polysorbate 20)
תרופה זו מכילה 0.4 מ"ג/מ"ל פוליסורבט 20. פוליסורנט עלול לגרום לתגובה אלרגית. ספר לרופא אם יש לך אלרגיות ידועות.

4. תופעות לוואי

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תופעות שאינן שכיחות - תופעות שמופיעות בעד משתמש אחד מתוך 100:
- חוסר יכולת לתיאום תנועות שרירים

עלון לרופא

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TALVEY 2 mg/mL solution for injection
One 1.5 mL vial contains 3 mg of talquetamab (2 mg/mL).

TALVEY 40 mg/mL solution for injection
One 1 mL vial contains 40 mg of talquetamab (40 mg/mL).

Talquetamab is a humanised immunoglobulin g4-proline, alanine, alanine (IgG4-PAA) bispecific antibody directed against G protein-coupled receptor family C group 5 member D (GPRC5D) and the cluster of differentiation 3 (CD3) receptors, produced in Chinese hamster ovary cells by recombinant DNA technology.

Excipients with known effect

Each dose contains 0.4 mg/mL of polysorbate 20.

For the full list of excipients, see section 6.1.

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4.4 Special warnings and precautions for use

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Excipients

Sodium
This medicinal product contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium-free'.

Polysorbate 20
This medicine contains 0.4 mg/mL of polysorbate 20. Polysorbates may cause allergic reactions.

4.8 Undesirable effects

Tabulated list of adverse reactions

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%)

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Dizziness*	Very common	42 (12%)	8 (2.4%)
Sensory neuropathy[5]	Very common	34 (10%)	0
Ataxia	Uncommon	1 (0.3%)	0
Respiratory, thoracic and mediastinal disorders			
Cough*	Very common	78 (23%)	0
Dyspnoea[6#]	Very common	39 (12%)	5 (1.5%)
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
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	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.

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[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.

5.1 Pharmacodynamic properties

Immunogenicity

In MonumenTAL-1, 363 ~~328~~ patients treated with subcutaneous talquetamab monotherapy at 0.4 mg/kg weekly or 0.8 mg/kg biweekly (every 2 weeks), with or without prior T cell redirection therapy, were evaluated for antibodies to talquetamab. Following treatment 0.4 mg/kg weekly or 0.8 mg/kg biweekly (every 2 weeks), 130 ~~106~~ of 363 ~~328~~ patients (~~32.3~~ 35.8%) developed anti-talquetamab antibodies. The incidence of treatment-emergent neutralising antibodies against talquetamab was 18.2% (66/363).
There was no clinically meaningful impact of anti-talquetamab antibodies on the pharmacokinetics, safety, or effectiveness of talquetamab.

~~The limited number of anti-talquetamab antibody (ADA) positive subjects and the lack of information of the neutralising ADA, preclude drawing a definite conclusion regarding the effect of the neutralising ADAs on clinical parameters.~~