HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use JUVMO safely and effectively. See full prescribing information for JUVMO.

JUVMO™ (tavapadon) tablets, for oral use
Initial U.S. Approval: 2026

INDICATIONS AND USAGE

JUVMO is a non-ergot dopamine agonist indicated for the treatment of Parkinson's disease in adults. (1)

DOSAGE AND ADMINISTRATION

- JUVMO is taken orally once daily, with or without food. (2.1)
- See Table 1 for the recommended titration schedule. (2.1)
- Recommended maintenance dosage is 5 mg orally once daily. The dosage may be increased to a maximum of 15 mg once daily based on tolerability and clinical response. (2.1)

DOSAGE FORMS AND STRENGTHS

Tablets: 0.25 mg, 1 mg, 5 mg, 10 mg, and 15 mg (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- May cause hypotension/orthostatic hypotension. (5.1)
- May cause problems with impulse control or compulsive behaviors. Consider dose reductions or stopping JUVMO. (5.2)
- May cause hallucinations and psychotic-like behavior. The risk of hallucinations may be increased when co-administered with strong CYP3A inhibitors during the maintenance phase. (5.3)
- May cause dyskinesia or exacerbate pre-existing dyskinesia. (5.4)

ADVERSE REACTIONS

- Most common adverse reactions (≥ 5%) for JUVMO without concomitant levodopa were nausea, headache, dizziness, fatigue, dysgeusia, vomiting, dry mouth, and anxiety. (6.1)
- Most common adverse reactions (≥ 5%) for JUVMO with concomitant levodopa were nausea, dyskinesia, dizziness, headache, hallucinations, and orthostatic hypotension. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact AbbVie Inc. at 1-800-633-9110 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Avoid concomitant use of strong or moderate CYP3A inhibitors during titration and strong CYP3A inducers during titration and maintenance of JUVMO. (2.2, 7.1)
- Recommended JUVMO dosage modifications during maintenance dosing:
  - Strong and moderate CYP3A inhibitors: Decrease dosing frequency. (2.2, 7.1)
  - Strong CYP3A inducers: Concomitant use is not recommended. (2.3, 7.1)
  - Moderate CYP3A inducers (long-term): Increase dosing frequency. (2.3, 7.1)
- CYP3A substrates: If JUVMO is used concomitantly with sensitive CYP3A substrates or CYP3A substrates where minimal concentration changes may lead to loss of efficacy, consider a dosage modification of such substrates when initiating or discontinuing JUVMO. (7.2)
- CYP2C8 substrates: If JUVMO is used concomitantly with sensitive CYP2C8 substrates or CYP2C8 substrates where minimal concentration changes may increase the risk of adverse reactions, consider a dosage reduction of such substrates. (7.2)
- BCRP Substrates: If JUVMO is used concomitantly with BCRP substrates, consider a reduction in dosage of BCRP substrates as clinically appropriate. (7.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Dosing Recommendations
2.2 Dosage Modifications for CYP3A Inhibitors
2.3 Dosage Modifications for CYP3A Inducers
2.4 Missed Dose
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Hypotension/Orthostatic Hypotension
5.2 Impulse Control/Compulsive Behaviors
5.3 Hallucinations and Psychotic-like Behavior
5.4 Dyskinesia
6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
7 DRUG INTERACTIONS
7.1 Effect of Other Drugs on JUVMO
7.2 Effect of JUVMO on Other Drugs
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.4 Pediatric Use
8.5 Geriatric Use
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
14.1 Parkinson's Disease (without Concomitant Levodopa)
14.2 Parkinson's Disease (with Concomitant Levodopa)
16 HOW SUPPLIED/STORAGE AND HANDLING
16.1 How Supplied
16.2 Storage and Handling
17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

JUVMO is indicated for the treatment of Parkinson's disease (PD) in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Recommendations

Administer JUVMO orally once daily with or without food.

The recommended dosage and titration are included in Table 1.

The JUVMO titration pack is recommended for patients initiating therapy with JUVMO to provide doses consistent with the recommended titration schedule to reach the 5 mg maintenance dosage *[see How Supplied/Storage and Handling (16.1)]*.

Table 1: Recommended Dosage

Titration Regimen*	
Treatment Days	**JUVMO Dosage**
Days 1 to 4	0.25 mg once daily
Days 5 to 8	0.5 mg once daily
Days 9 to 12	0.75 mg once daily
Days 13 to 16	1 mg once daily
Days 17 to 20	1.5 mg once daily
Days 21 to 24	2.25 mg once daily
Days 25 to 40	3 mg once daily
Maintenance Dosage	
Day 41 and thereafter	5 mg once daily
Maximum Dosage	
If needed, based on tolerability and clinical response, the maintenance dose may be increased in increments of 5 mg approximately every 15 days to the maximum recommended daily dosage.	15 mg once daily

* Dose and titration should be guided by tolerability and clinical response. If required, longer intervals between dose adjustment can be used.

2.2 Dosage Modifications for CYP3A Inhibitors

Strong or Moderate CYP3A Inhibitors *[see Warnings and Precautions (5.3), Drug Interactions (7.1)]*

JUVMO Titration

Avoid concomitant use of strong or moderate CYP3A inhibitors during titration of JUVMO.

JUVMO Maintenance when Initiating Strong or Moderate CYP3A Inhibitors

Follow the JUVMO dosage modifications in Table 2 when initiating a strong or moderate CYP3A inhibitor for patients already on JUVMO maintenance.

Table 2: Dosage Modifications When Initiating a CYP3A Inhibitor in Patients Already on JUVMO Maintenance

Current JUVMO Maintenance Dosage	Recommended JUVMO Modification for Maintenance Dosage	
	When Initiating a Strong CYP3A Inhibitor	When Initiating a Moderate CYP3A Inhibitor
5 mg once daily	5 mg every 7 days	5 mg every 3 days
10 mg once daily	10 mg every 7 days	10 mg every 3 days
15 mg once daily	15 mg every 7 days	15 mg every 3 days

Discontinuing CYP3A Inhibitors

Upon discontinuation of the strong or moderate CYP3A inhibitor, resume the JUVMO maintenance dosage that was used prior to the initiation of the CYP3A inhibitor. Monitor patients for clinical response and tolerability.

2.3 Dosage Modifications for CYP3A Inducers

Strong CYP3A Inducers *[see Drug Interactions (7.1)]*

Avoid concomitant use of strong CYP3A inducers during titration and maintenance of JUVMO.

Moderate CYP3A Inducers *[see Drug Interactions (7.1)]*

Initiating JUVMO Titration and Maintenance when on Long-Term Moderate CYP3A Inducers

Follow the JUVMO dosage modifications in Table 3 when initiating JUVMO titration and maintenance in patients who are already on long-term moderate CYP3A inducers.

Table 3: Dosage Modifications for Patients Already on Moderate CYP3A Inducers

Titration Regimen (requires two JUVMO titration packs)*	
Treatment Days	**JUVMO Dosage**
Days 1 to 4	0.25 mg twice daily
Days 5 to 8	0.5 mg twice daily
Days 9 to 12	0.75 mg twice daily
Days 13 to 16	1 mg twice daily
Days 17 to 20	1.5 mg twice daily
Days 21 to 24	2.25 mg twice daily
Days 25 to 40	3 mg twice daily
Maintenance Dosage	
Day 41 and thereafter	5 mg twice daily
Maximum Dosage	
If needed, based on clinical response and tolerability, the maintenance dosage may be increased to 5 mg three times a day. If further escalation is needed, the dose may be increased by 5 mg every 15 days,	45 mg daily (15 mg three times daily)

administered in divided doses (either twice a day or three times a day), to the maximum recommended daily dosage.	

* Use one JUVMO titration pack for the morning dose and the second JUVMO titration pack for the evening dose.

JUVMO Maintenance when Initiating Moderate CYP3A Inducers

For patients who are already on JUVMO maintenance dosage and start to take moderate CYP3A inducers, modifications to JUVMO dosing are provided below:

- Days 1 to 7 of concomitant use: continue the current maintenance dosage of JUVMO (5 mg, 10 mg, or 15 mg once daily).
- Day 8 and thereafter during concomitant use: increase the frequency of the maintenance dosage of JUVMO to twice daily. If needed, based on clinical response and tolerability, the maintenance dosage can be increased to three times daily.

Discontinuing CYP3A Inducers

Upon discontinuation of moderate CYP3A inducers, gradually reduce the JUVMO dosage to once daily. Monitor patients for clinical response and tolerability.

2.4 Missed Dose

If a dose of JUVMO is missed, take it as soon as remembered on the same day, but do not double the dose. Do not take a missed dose on the following day. Skip the missed dose and resume the regular dosing schedule.

3 DOSAGE FORMS AND STRENGTHS

Tablets supplied as:

- 0.25 mg: Round, orange, film-coated, with “NRS” debossed on one side and “025” on the other side
- 1 mg: Rectangle, orange, film-coated, with “NRS” debossed on one side and “1” on the other side
- 5 mg: Diamond, purple, film-coated, with “NRS” debossed on one side and “5” on the other side
- 10 mg: Oval, purple, film-coated, with “NRS” debossed on one side and “10” on the other side
- 15 mg: Rectangle, purple, film-coated, with “NRS” debossed on one side and “15” on the other side

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hypotension/Orthostatic Hypotension

Patients with PD may have an impaired capacity to respond to an orthostatic challenge. In clinical studies and clinical experience, dopaminergic medications appear to impair the systemic regulation of blood pressure, resulting in hypotension and/or orthostatic hypotension, especially during dose escalation. For these reasons, patients with PD being treated with JUVMO should be monitored for signs and symptoms of hypotension/orthostatic hypotension especially during dose escalation, and should be informed of this risk.

In Study 1 and Study 2 in patients with PD who were not taking levodopa *[see Clinical Studies (14.1)]*, orthostatic hypotension was reported in 5% of patients treated with JUVMO compared to 1% of patients who received placebo. Hypotension was reported in 4% of patients treated with JUVMO tablets compared to 1% on placebo.

In Study 3 in patients taking JUVMO as adjunctive therapy to fixed dose levodopa *[see Clinical Studies (14.2)]*, orthostatic hypotension was reported in 8% of patients treated with JUVMO compared to 2% of patients on placebo. Hypotension was reported in 4% of patients treated with JUVMO compared to 0.4% on placebo.

5.2 Impulse Control/Compulsive Behaviors

Patients may experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges while taking one or more of the medications that increase central dopaminergic tone and are generally used for the treatment of PD, including JUVMO. In some cases, although not all, these urges were reported to have stopped when the dose was reduced or the medication was discontinued.

In Study 1 and Study 2, impulse control disorders were reported in 1% of patients treated with JUVMO compared to no patients on placebo. In Study 3, impulse control disorders were reported in 2% of patients treated with JUVMO compared to 1% of patients on placebo.

Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while being treated with JUVMO. Consider reducing the dose or discontinuing JUVMO if a patient develops such urges.

5.3 Hallucinations and Psychotic-like Behavior

Medications for the treatment of PD, including JUVMO, can have effects on thinking and behavior. This abnormal thinking and behavior can consist of one or more of a variety of manifestations including paranoid ideation, delusions, hallucinations, confusion, psychotic-like behavior, symptoms of mania (e.g., insomnia, psychomotor agitation), disorientation, aggressive behavior, agitation, and delirium.

In Study 1 and Study 2, hallucination was reported in 3% of patients treated with JUVMO compared to no patients on placebo. In Study 3, when added as an adjunct to a fixed dose of

levodopa, hallucination was reported in 7% of patients treated with JUVMO compared to 1% of patients on placebo.

Age appears to increase the risk of hallucinations in patients taking JUVMO. In Study 1 and Study 2, among patients 65 years of age and older, hallucination was reported in 4% of patients treated with JUVMO compared to no patients on placebo. In Study 3, among patients 65 years of age and older, hallucination was reported in 9% of patients treated with JUVMO compared to 1% of patients on placebo.

The risk of hallucination may be increased when JUVMO is co-administered with strong CYP3A inhibitors during the maintenance phase *[see Dosage and Administration (2.2)]*.

Consider the risks and benefits prior to initiating treatment with JUVMO in patients with a major psychotic disorder because of the risk of exacerbating psychosis. In addition, certain medications used to treat psychosis may exacerbate the symptoms of PD. Consider stopping JUVMO if hallucinations or psychotic-like behaviors occur.

5.4 Dyskinesia

JUVMO may cause or exacerbate pre-existing dyskinesia. In Study 1 and Study 2, 0.6% of patients with PD treated with JUVMO reported dyskinesia compared with no patients on placebo. In Study 3, 10.0% of patients treated with JUVMO reported dyskinesia compared to 2% on placebo. Consider decreasing the dosage of JUVMO or other dopaminergic medications if dyskinesia occurs.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Hypotension/Orthostatic Hypotension *[see Warnings and Precautions (5.1)]*
- Impulse Control/Compulsive Behaviors *[see Warnings and Precautions (5.2)]*
- Hallucinations and Psychotic-like Behavior *[see Warnings and Precautions (5.3)]*
- Dyskinesia *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of JUVMO was evaluated in 1,279 patients with PD who received at least one dose of JUVMO. Of the patients with PD who received JUVMO, 870 were treated for at least 6 months and 630 were treated for at least 1 year.

JUVMO without Concomitant Levodopa

Study 1 evaluated fixed doses of once daily JUVMO 5 mg (n=177) and JUVMO 15 mg (n=177) compared to placebo (n=175). Study 2 evaluated doses of JUVMO 5 mg to 15 mg unless prevented by intolerance (n=151) compared to placebo (n=153) *[see Clinical Studies (14.1)]*.

In Study 1 and Study 2 combined (n=833 total patients), the most common adverse reactions that occurred in ≥ 5% of patients treated with JUVMO were nausea, headache, dizziness, fatigue, dysgeusia, vomiting, dry mouth, and anxiety. Adverse reactions led to discontinuation of JUVMO in 100 of 505 patients (20%). Of the 100 patients receiving JUVMO who discontinued because of an adverse reaction, 85 (85%) did so during the titration and/or adjustment phases. The most common adverse reactions leading to discontinuation in patients taking JUVMO were nausea, dizziness, headache, and vomiting.

Table 4 presents the adverse reactions that occurred in ≥ 3% of patients treated with JUVMO and with a difference of ≥ 2% between the JUVMO and the placebo group in Study 1 and Study 2.

Table 4: Adverse Reactions that Occurred in ≥ 3% of Patients with Parkinson's Disease Treated with JUVMO and ≥ 2% Difference from Placebo in Study 1 and Study 2 (without Concomitant Levodopa)

Adverse Reaction	JUVMO (N=505) %	Placebo (N=328) %
Nausea	27	2
Headache[a]	17	5
Dizziness	14	4
Fatigue[b]	10	3
Dysgeusia	8	0
Vomiting	7	<1
Dry mouth	5	<1
Anxiety	5	2
Hypotension	4	1
Dyspepsia	4	1
Abnormal dreams	4	<1
Orthostatic hypotension	4	<1
Hallucination[c]	3	0
Gastroesophageal reflux disease	3	<1
Constipation	3	1

[a] Headache includes multiple related terms
[b] Fatigue includes asthenia
[c] Hallucination includes multiple related terms

JUVMO with Concomitant Levodopa

Patients in Study 3 were on a fixed dose of levodopa and were titrated to JUVMO 15 mg once daily unless prevented by intolerance, resulting in maintenance doses between 5 mg and 15 mg (n=251), compared to placebo (n=254). The most common adverse reactions that occurred in ≥ 5% of patients treated with JUVMO were nausea, dyskinesia, dizziness, headache, hallucinations, and orthostatic hypotension. Adverse reactions led to discontinuation of JUVMO

in 43 of 251 patients (17%). Of the 43 patients receiving JUVMO who discontinued because of an adverse reaction, 38 (88%) did so during the titration and adjustment phases. The most common adverse reactions leading to discontinuation included nausea, dyskinesia, visual hallucination, and dizziness.

Table 5 summarizes the adverse reactions that occurred in ≥ 3% of patients who received JUVMO and with a difference of ≥ 2% between the JUVMO and the placebo groups in Study 3.

Table 5: Adverse Reactions that Occurred in ≥ 3% of Patients with Parkinson's Disease Treated with JUVMO and ≥ 2% Difference from Placebo in Study 3 (with Concomitant Levodopa)

Adverse Reaction	JUVMO (N=251) %	Placebo (N=254) %
Nausea	14	4
Dyskinesia	10	2
Dizziness	8	3
Headache[a]	7	3
Hallucination[b]	7	1
Orthostatic hypotension	6	1
Hypotension	4	<1
Abdominal pain	3	<1
Asthenia	3	0

[a] Headache includes multiple related terms
[b] Hallucination includes multiple related terms

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on JUVMO

Table 6 describes drug interactions where concomitant use of another drug affects the use of JUVMO.

Table 6: Drug Interactions: Concomitant Use of Other Drugs that Affect the Use of JUVMO

Strong and Moderate CYP3A Inhibitors	
Prevention or Management	If JUVMO is used with a strong or moderate CYP3A inhibitor during JUVMO maintenance, reduce JUVMO dosage frequency *[see Dosage and Administration (2.2)]*.
Mechanism and Clinical Effect(s)	Tavapadon is CYP3A substrate. Concomitant use of strong and moderate CYP3A inhibitors increase the exposure of tavapadon, which may increase the risk of adverse reactions *[see Clinical Pharmacology (12.3)]*. Concomitant use of strong CYP3A inhibitors may increase the risk of hallucinations *[see Warnings and Precautions (5.3), Clinical Pharmacology (12.3)]*.

Strong and Moderate CYP3A Inducers	
Prevention or Management	Concomitant use of JUVMO with a strong CYP3A inducer is not recommended *[see Dosage and Administration (2.3)]*. If JUVMO is used in a patient already on a long-term moderate CYP3A inducer, increase JUVMO dosage frequency *[see Dosage and Administration (2.3)]*.
Mechanism and Clinical Effect(s)	Tavapadon is CYP3A substrate. Concomitant use of strong or moderate CYP3A inducer decreases the exposure of tavapadon which may result in reduced JUVMO efficacy *[see Clinical Pharmacology (12.3)]*.

7.2 Effect of JUVMO on Other Drugs

Table 7 describes drug interactions where JUVMO affects concomitant use of another drug.

Table 7: Drug Interactions: JUVMO Affecting Other Drugs with Concomitant Use

CYP3A Substrates	
Prevention or Management	Consider a dose modification of sensitive CYP3A substrates or CYP3A substrates where minimal concentration changes may lead to loss of efficacy, as clinically appropriate, when initiating or discontinuing JUVMO.
Mechanism and Clinical Effect(s)	JUVMO is an inducer of CYP3A *[see Clinical Pharmacology (12.3)]*. Concomitant use of JUVMO may decrease the concentrations of CYP3A substrates.
CYP2C8 Substrates	
Prevention or Management	Consider a dosage reduction of sensitive CYP2C8 substrates or CYP2C8 substrates where minimal concentration changes may increase the risk of severe adverse reactions, as clinically appropriate, when concomitantly used with JUVMO.
Mechanism and Clinical Effect(s)	JUVMO is an inhibitor of CYP2C8 *[see Clinical Pharmacology (12.3)]*. Concomitant use of JUVMO may increase the plasma concentrations of CYP2C8 substrates.
BCRP Substrates	
Prevention or Management	Consider a dosage reduction of BCRP substrates, as clinically appropriate, when concomitantly used with JUVMO.
Mechanism and Clinical Effect(s)	JUVMO is an inhibitor of efflux transporter BCRP *[see Clinical Pharmacology (12.3)]*. Concomitant use of JUVMO may increase the exposure of BCRP substrates.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of JUVMO in pregnant women. In animal studies, administration of tavapadon during organogenesis (rats and rabbits) did not result in adverse developmental effects at exposures greater than those used clinically (see Data). Following administration of tavapadon throughout pregnancy and lactation (rats), there were adverse effects on postnatal growth at exposures 7 times those used clinically (see Data).

The estimated background risk of major birth defects and of miscarriage in the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

There were no adverse embryo-fetal development effects following oral administration of tavapadon to pregnant rats (5, 15 and 120 mg/kg/day) and rabbits (1, 3 and 10 mg/kg/day) during organogenesis at the 120 mg/kg/day dose in rats (10.3 times the human AUC at the maximum recommended human dose [MRHD]) or the 10 mg/kg/day dose in rabbits (1.8 times the human AUC at the MRHD).

Oral administration of tavapadon to rats (5, 15, or 120 mg/kg/day) throughout gestation and lactation resulted in a reversible decrease in female pup body weights at 120 mg/kg/day. In male pups, there was a delay in preputial separation at all doses.

8.2 Lactation

Risk Summary

There are no data on the presence of tavapadon in human milk, the effects of tavapadon on the breastfed infant, or the effects of tavapadon on milk production. Tavapadon was present in the milk when administered to lactating rats.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for JUVMO and any potential adverse effects on the breastfed infant from JUVMO or from the underlying maternal condition.

8.4 Pediatric Use

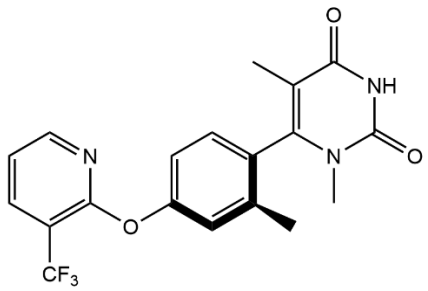
Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the 1,279 patients who received JUVMO in clinical studies, 691 (54%) were ≥ 65 years of age and 166 (13%) were ≥ 75 years of age. Patients aged 65 years and older who are treated with JUVMO are at an increased risk of hallucinations *[see Warnings and Precautions (5.3)]*.

11 DESCRIPTION

The active ingredient of JUVMO is tavapadon, a non-ergot dopamine agonist. The chemical name is (*S*)-1,5-dimethyl-6-(2-methyl-4-{[3-(trifluoromethyl) pyridin-2-yl]oxy}phenyl)pyrimidine- 2,4(1*H*,3*H*)-dione. Its molecular formula is $C_{19}H_{16}F_3N_3O_3$ and its molecular weight is 391.35 Daltons. The chemical structure is:



Tavapadon is a white to pale-yellow solid that is practically insoluble in water.

JUVMO tablets are intended for oral administration. Each film-coated tablet contains 0.25 mg, 1 mg, 5 mg, 10 mg, or 15 mg tavapadon. Inactive ingredients include:

- 0.25 mg and 1 mg tablets: Lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, red iron oxide, sodium starch glycolate, talc, titanium dioxide, and yellow iron oxide.
- 5 mg, 10 mg, and 15 mg tablets: Carmine, FD&C Blue No. 2, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, talc, and titanium dioxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tavapadon is a selective partial agonist at the dopamine D1 and D5 receptor subtypes (D_1/D_5).

12.2 Pharmacodynamics

Cardiac Electrophysiology

At the maximum recommended JUVMO dosage of 15 mg once daily, a mean increase in the QTc interval >20 ms is unlikely.

12.3 Pharmacokinetics

Absorption

Following oral administration of JUVMO, tavapadon is absorbed with peak plasma concentrations (C_{max}) at approximately 2 to 4 hours. Tavapadon displays dose-proportional pharmacokinetics within the maintenance dose range of 5 mg to 15 mg.

Effect of Food

When JUVMO was administered with a high-fat/high-calorie meal, the food effect was not significant (AUC_{τ} and C_{max} were increased by approximately 10% and 12%, respectively, with no effect on median time to C_{max}). JUVMO was administered without regard to food in clinical efficacy studies.

Distribution

Tavapadon plasma protein binding is 93% (primarily albumin). The apparent volume of distribution of tavapadon is 63.5 L.

Elimination

Metabolism

Tavapadon and its major inactive metabolite M4 are primarily metabolized by CYP3A. The AUC ratio of M4 to tavapadon is approximately 1.4.

Excretion

Unchanged tavapadon was a minor component in both urine and feces (less than 1%). Metabolite M4 accounted for less than 5% of the administered dose in both urine and feces.

The mean elimination half-life of tavapadon is approximately 25.5 hours.

Specific Populations

No clinically significant differences in pharmacokinetics of tavapadon were observed based on age (21 years to 79 years), sex, body weight (56 kg to 119 kg), race, severe renal impairment not requiring dialysis (eGFR < 30 mL/min estimated by CKD-EPI equation), mild hepatic impairment (Child-Pugh Class A), or moderate hepatic impairment (Child-Pugh Class B). The effects of renal impairment in patients with eGFR < 15 mL/min or on dialysis and severe hepatic impairment (Child-Pugh Class C) on tavapadon pharmacokinetics have not been studied.

Drug Interaction Studies

Clinical Studies and Model-based Approaches

Strong CYP3A Inhibitors

Concomitant administration of itraconazole (200 mg daily for 14 days), a strong CYP3A inhibitor, with JUVMO increased tavapadon AUC_{τ} and C_{max} by 5-fold and 4-fold, respectively. When a strong CYP3A inhibitor is initiated during tavapadon maintenance therapy (5, 10, or 15 mg doses) with a reduced dosing frequency of once-weekly, steady-state $AUC_{0–24}$ and $C_{max, daily}$ are predicted to fluctuate between +84% to -23% and +50% to -41%, respectively, across the 7-day dosing interval relative to once daily dosing of JUVMO without an inhibitor, with values highest on Day 1 of the dosing week *[see Dosage and Administration (2.2), Warnings and Precautions (5.3), Drug Interactions (7.1)]*.

Moderate CYP3A Inhibitors

Concomitant administration of fluconazole (200 mg daily), a moderate CYP3A inhibitor, with 15 mg JUVMO at steady-state is predicted to increase the AUC_{τ} and C_{max} of tavapadon by approximately 2.6-fold and 2.3-fold, respectively. When a moderate CYP3A inhibitor is initiated during tavapadon maintenance therapy (5, 10, or 15 mg doses) with a reduced dosing frequency

from once daily to once every 3 days, steady-state $AUC_{0–24}$ and $C_{max,\ daily}$ fluctuate between +14% to -40% and +1 to -43%, respectively from Day 1 to Day 3 of the dosing interval, relative to once daily dosing without an inhibitor. Exposures are predicted to be lowest on Day 3 of the once every 3 days dosing interval *[see Dosage and Administration (2.2), Drug Interactions (7.1)]*.

Strong CYP3A Inducers

Concomitant administration of carbamazepine (300 mg twice daily), a strong CYP3A inducer, with JUVMO decreased tavapadon AUC_{τ} and C_{max} by 63% and 49%, respectively *[see Dosage and Administration (2.3), Drug Interactions (7.1)]*.

Moderate CYP3A Inducers

Concomitant administration of efavirenz (600 mg), a moderate CYP3A inducer, with 15 mg JUVMO is predicted to decrease the AUC_{τ} and C_{max} of tavapadon by 70% and 58%, respectively. When a moderate CYP3A inducer is initiated during maintenance therapy (5, 10, or 15 mg doses) of tavapadon, with an increased dosing frequency from once daily to three times daily, steady state $AUC_{0–24}$ and $C_{max,daily}$ are not predicted to differ significantly relative to once daily dosing without an inducer *[see Dosage and Administration (2.3), Drug Interactions (7.1)]*.

Effects of Tavapadon on Other Drugs

Tavapadon is predicted to cause clinically relevant induction of CYP3A, inhibition of CYP2C8, and BCRP *[see Drug Interactions (7.2)]*.

In Vitro Assessment of Drug Interactions

Cytochrome P450 (CYP450) Enzymes: Tavapadon and M4 are substrates of CYP3A, but are not substrates of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP2D6. Tavapadon and M4 are not reversible inhibitors of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, or CYP3A/5.

Tavapadon is a time-dependent inhibitor of CYP2C8. Tavapadon and M4 did not demonstrate time-dependent inhibition of CYP1A2, 2B6, 2C9, 2C19, 2D6, or 3A4.

Tavapadon and M4 are inducers of CYP3A, but are not inducers of CYP1A2 or CYP2B6.

UDP-Glucuronosyltransferase (UGT): Tavapadon is an inhibitor of UGT1A9 but is not expected to result in clinically significant drug interactions. M4 is not an inhibitor of UGT1A9.

Tavapadon and M4 are not inhibitors of UGT1A1, 1A3, 1A4, 1A6, 2B7, or 2B15.

Transporter Systems: Tavapadon is a substrate for P-gp and BCRP, but is not expected to result in clinically significant drug interactions. Tavapadon and M4 are not substrates of OATP1B1, OATP1B3, OCT1, OCT2, OAT1, OAT3, MATE1, or MATE2-K.

Tavapadon inhibits BCRP, but not P-gp, OATP1B1, OATP1B3, OCT1, OCT2, OAT1, or OAT3.

Tavapadon is an inhibitor of MATE1, while M4 is an inhibitor of both MATE1 and MATE2-K, but are not expected to result in clinically significant drug interactions.

M4 is not an inhibitor of BCRP, P-gp, OATP1B1, OATP1B3, OCT1, OCT2, OAT1, or OAT3.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies of tavapadon were conducted in Tg.rasH2 mice at oral doses of 10, 30 and 100 mg/kg/day for up to 26-weeks and in male and female rats at oral doses of 5, 15, 50 mg/kg/day and 2, 10, 120 mg/kg/day, respectively, for up to 2 years.

In the 26-week study, mice had an increased incidence of hepatocellular adenomas at 100 mg/kg/day. In the 2-year study in rats, female rats exhibited an increase in pancreatic and whole body adenocarcinoma at the high dose 120 mg/kg/day. Tavapadon exposure at this dose was 14-fold greater than the exposure at the MRHD. Male rats had an increased incidence of Leydig cell tumors at ≥ 15 mg/kg/day, and female rats showed increased incidences of uterine/cervical tumors at ≥ 10 mg/kg/day. The endocrine mechanism involved in the production of these tumors (prolactin reduction) in rats is not considered relevant to humans.

Mutagenesis

Tavapadon was not mutagenic or clastogenic in in vitro (bacterial mutagenicity and micronucleus TK6 cells) and in vivo (rat peripheral blood micronucleus) assays.

Impairment of Fertility

Tavapadon was orally administered to male (15, 50, 150 mg/kg/day) and female (0.5, 1.5, or 5 mg/kg/day) rats prior to and during mating and continuing in females through gestation day 7. There were no adverse effects on fertility or reproductive performance. Plasma exposures (AUC) at the highest dose tested are approximately 9.3 times (males) and 3.1 times (females) the MRHD.

14 CLINICAL STUDIES

14.1 Parkinson's Disease (without Concomitant Levodopa)

The efficacy of JUVMO for the treatment of PD in adults not on concomitant levodopa was established in two 27-week randomized, multicenter, double-blind, placebo-controlled studies, Study 1 (NCT04201093) and Study 2 (NCT04223193). Both studies enrolled PD patients with the following criteria:

- diagnosis consistent with the UK Parkinson's Disease Society Brain Bank diagnostic criteria;
- modified Hoehn and Yahr stage of 1, 1.5, or 2;
- Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II score ≥2 and an MDS-UPDRS Part III score ≥10;
- not receiving medications to treat Parkinson's disease (e.g., levodopa) other than concomitant stable dose of an MAO-B inhibitor.

In each study, the dose of JUVMO was gradually titrated from 0.25 mg once daily to the target dose, which was then maintained for the remainder of the 27-week treatment period. Patients who could not achieve the 5 mg dose during the Titration Phase or tolerate their maintenance

doses were discontinued from the study *[see Adverse Reactions (6.1)]*. Patients that completed the 27-week treatment period had the option to receive JUVMO in a 58-week open-label treatment period.

Efficacy was determined based on the change from baseline in the MDS-UPDRS Part II score at Week 26. The MDS-UPDRS Part II contains 13 questions related to activities of daily living, which are scored from 0 (normal) to 4 (maximal severity) for a maximum (worst) score of 52. A reduction in the score represents improvement, and a beneficial change from baseline appears as a negative number.

Study 1

In Study 1, 529 patients were randomized 1:1:1 to receive JUVMO 5 mg (N = 177), JUVMO 15 mg (N = 177), or placebo (N = 175) once daily. Patients were titrated based on their randomized arm to either 5 mg or 15 mg dose based on the recommended titration schedule *[see Dosage and Administration (2.1)]*.

Patients had a mean age of 63.7 years (range: 40 to 80 years), 65% were male, 97% were White, and 6% were Hispanic. The mean duration of PD at baseline was 0.8 years (range: 0 to 3 years). The mean MDS-UPDRS Part II score at baseline was 7.4 and was similar across treatment groups.

There was a statistically significant difference in mean change from baseline in the MDS-UPDRS Part II score for patients receiving JUVMO 5 mg and 15 mg, compared to patients receiving placebo, at Week 26 (<0.0001). These results are summarized in Table 8.

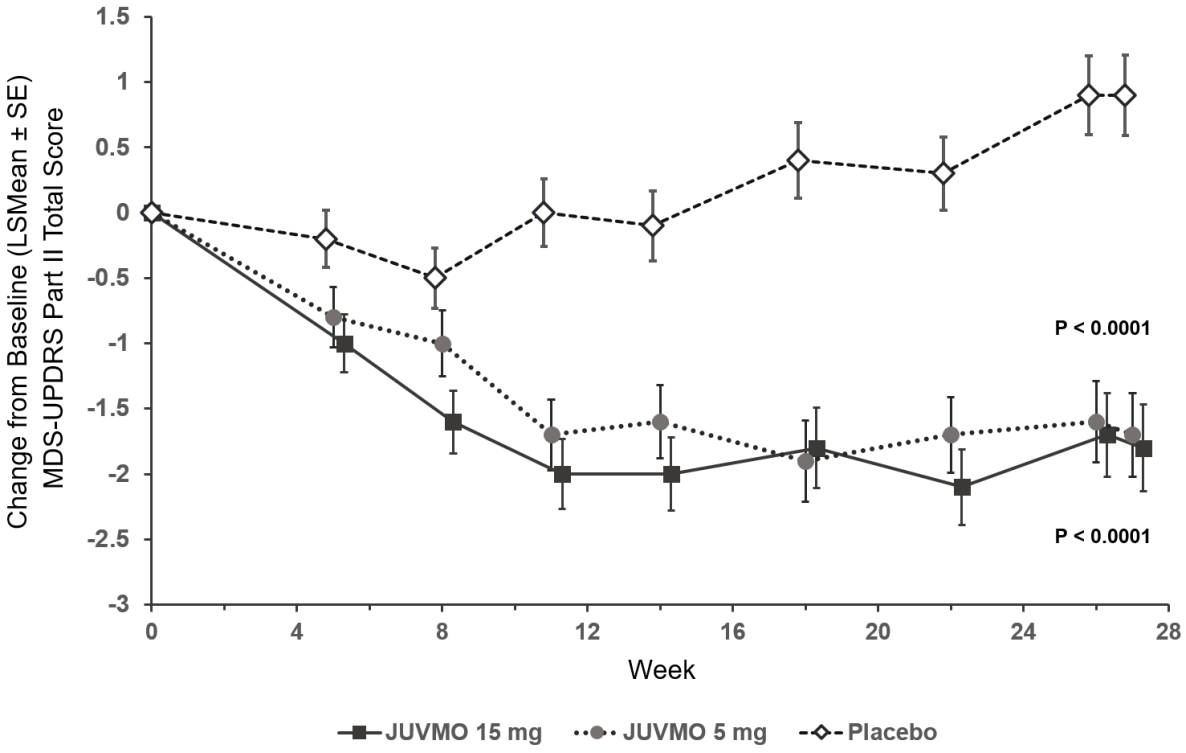
Table 8: Change from Baseline to Week 26 in MDS-UPDRS Part II in Patients with Parkinson's Disease Not on Concomitant Levodopa in Study 1

	JUVMO 5 mg (N = 174)	**JUVMO 15 mg (N = 172)**	**Placebo (N = 174)**
MDS-UPDRS[a] Part II Score			
Baseline (SD)	7.1 (4.00)	7.7 (4.26)	7.4 (3.83)
LS mean change (SE) from baseline to Week 26	-1.6 (0.31)	-1.7 (0.32)	0.9 (0.30)
LSMD vs Placebo (95% CI)	-2.5 (-3.3, -1.7)	-2.6 (-3.4, -1.7)	
p-value	<0.0001	<0.0001	

[a] Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale
SD=standard deviation; LS=least squares; SE=standard error; LSMD=least squares mean difference; CI=confidence interval

Figure 1 shows the results over time for the MDS-UPDRS Part II for Study 1.

Figure 1: Study 1 LS Mean (SE) Change From Baseline in MDS-UPDRS Part II Score by Trial Visit (mITT Population)



mITT=modified intent-to-treat

Study 2

In Study 2, 304 patients were randomized 1:1 to receive JUVMO 5 mg to 15 mg (N = 151) or placebo (N = 153) once daily. Patients in the JUVMO arm were titrated to receive 5 mg to 15 mg according to the recommended titration schedule unless limited by tolerability *[see Dosage and Administration (2.1)]*.

Patients had a mean age of 62.9 years (range: 40 to 80 years), 56% were male, 88% were White, 11% were Asian, and 5% were Hispanic. The mean duration of PD at baseline was 0.9 years (range: 0 to 3 years). The mean MDS-UPDRS Part II score at baseline was 7.1 and was similar between treatment groups.

There was a statistically significant difference in mean change from baseline in MDS-UPDRS Part II score for patients receiving JUVMO, compared to patients receiving placebo, at Week 26 ($p<0.0001$). These results are summarized in Table 9.

Table 9: Change from Baseline to Week 26 in MDS-UPDRS Part II in Patients with Parkinson's Disease Not on Concomitant Levodopa in Study 2

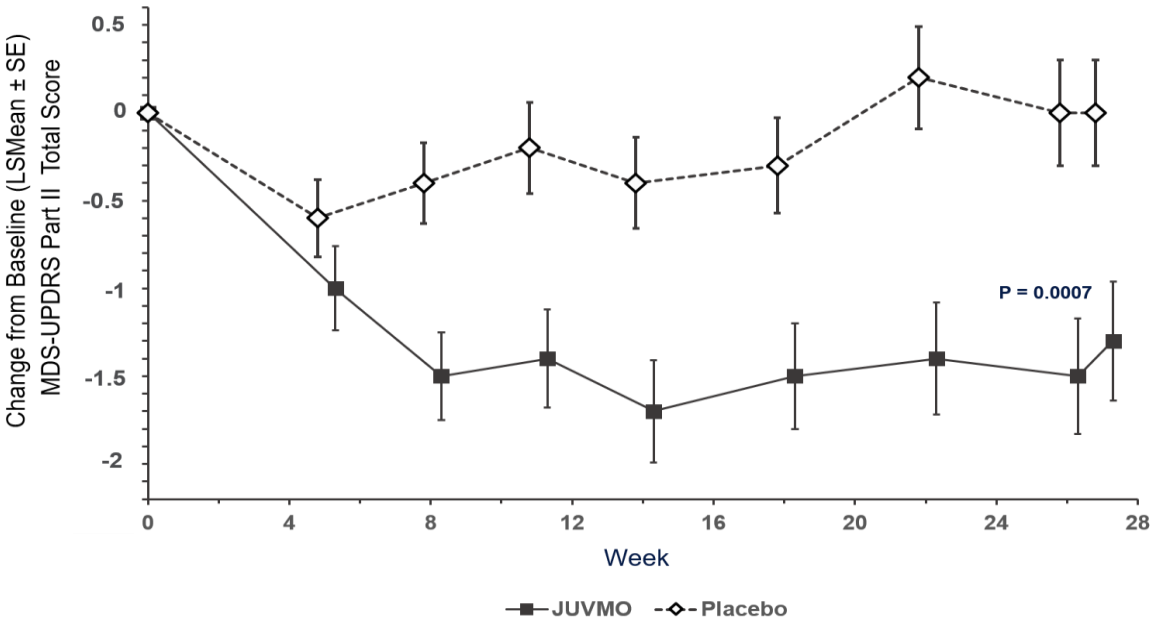
	JUVMO (N = 150)	**Placebo (N = 151)**
MDS-UPDRS[a] Part II Score		
Baseline (SD)	7.4 (4.32)	6.8 (3.86)

LS mean change (SE) from baseline to Week 26	-1.5 (0.33)	0.0 (0.30)
LSMD vs Placebo (95% CI)	-1.5 (-2.4, -0.6)	
p-value	0.0007	

[a] Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale
SD=standard deviation; LS=least squares; SE=standard error; LSMD=least squares mean difference; CI=confidence interval

Figure 2 shows the results over time for the MDS-UPDRS Part II in Study 2.

Figure 2: Study 2 LS Mean (SE) Change From Baseline of MDS-UPDRS Part II Score by Trial Visit (mITT Population)



mITT=modified intent-to-treat

14.2 Parkinson's Disease (with Concomitant Levodopa)

The efficacy of JUVMO for the treatment of PD as adjunctive therapy to levodopa was established in a 27-week, double-blind, randomized, placebo-controlled, parallel-group, flexible-dose trial, Study 3 (NCT04542499). Study 3 enrolled adult patients with the following criteria:

- diagnosis of PD consistent with the UK Parkinson's Disease Society Brain Bank diagnostic criteria;
- modified Hoehn and Yahr score of 2, 2.5, or 3 in the "ON" state;
- minimum of 2.5 hours of "OFF" time on 2 consecutive days;

- minimum stable dose of levodopa of 400 mg per day divided at least 3 or 4 times daily depending on dose formulation; and a good response to levodopa in the judgement of the investigator.

In this trial, 507 patients were randomized 1:1 to receive JUVMO 5 mg to 15 mg (N = 252) or placebo (N = 255) once daily as adjunctive therapy to the pre-study levodopa dose. No changes in levodopa were allowed during study participation.

Patients had a mean age of 64.9 years (range: 43 to 80 years), 63% were male, 97% were White, and 5% were Hispanic. The mean duration of PD at baseline was 6.7 years (range: 0.1 to 30.9 years). The mean total ON time without troublesome dyskinesia at baseline was 10.0 hours and was similar between treatment groups.

The primary efficacy measure was the change from baseline in the total daily ON time without troublesome dyskinesia at Week 26 based on the self-completed home diary for motor function status (Hauser diary).

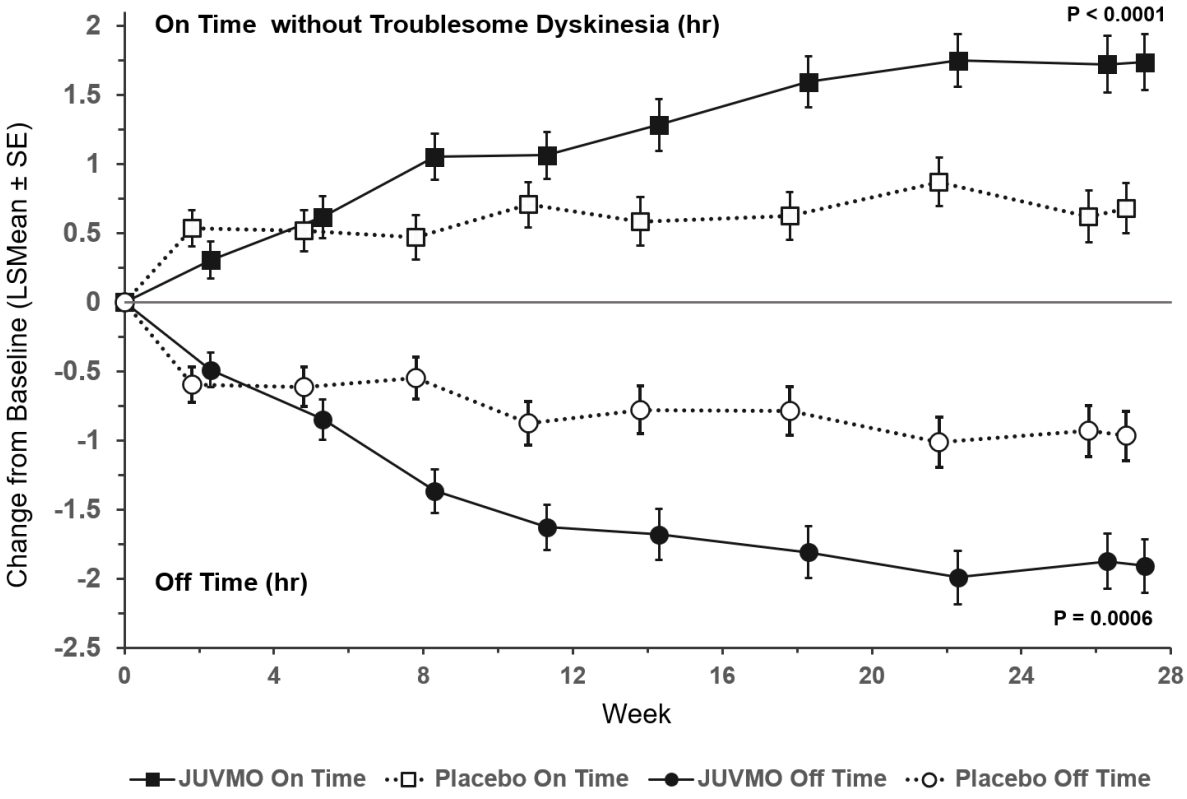
The key secondary efficacy measure was change from baseline in total daily OFF time to Week 26. JUVMO demonstrated a statistically significant increase in daily ON time without troublesome dyskinesia in patients treated with JUVMO compared to placebo ($p<0.0001$; see Table 10). There was also a statistically significant reduction in daily OFF time in patients treated with JUVMO compared to placebo ($p=0.0006$; see Table 10).

Table 10: Change from Baseline to Week 26 in Primary and Key Secondary Measures in Study 3

	JUVMO (N = 242)	**Placebo (N = 245)**
Primary Measure		
Total daily ON time without troublesome dyskinesia (hours)		
Baseline Mean (SD)	9.9 (2.58)	10.2 (2.58)
Change from baseline to Endpoint Week 26 Mean (SD)	1.7 (0.21)	0.6 (0.19)
LS Mean (SE) Difference	1.1 (0.6, 1.7)	
p-value	<0.0001	
Secondary Measure		
Total daily OFF time (hours)		
Baseline Mean (SD)	5.6 (2.26)	5.4 (2.36)
Change from Baseline to Endpoint Week 26 Mean (SD)	-1.9 (0.20)	-0.9 (0.18)
LS Mean (SE) Difference	-0.9 (-1.5, -0.4)	
p-value	0.0006	

Figure 3 shows results over time according to treatment for the efficacy variables (mean change from baseline to week 26 in the total daily mean ON time without troublesome dyskinesia and in OFF time based on the PD diary).

Figure 3: LS Mean (SE) Change from Baseline in ON Time (Hours) Without Troublesome Dyskinesia and in OFF Time (Hours) by Study Visit in Study 3 (mITT Population)



mITT=modified intent-to-treat

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

JUVMO (tavapadon) tablets are supplied in the following configurations:

Tablet Strength	Description	Package Configuration	NDC Code
5 mg	Purple, film-coated, diamond, with “NRS” debossed on one side and “5” on the other side	Bottle of 30	0074-6105-30

10 mg	Purple, film-coated, oval, with "NRS" debossed on one side and "10" on the other side	Bottle of 30	0074-6210-30
15 mg	Purple, film-coated, rectangle, with "NRS" debossed on one side and "15" on the other side	Bottle of 30	0074-6315-30
Titration Pack	0.25 mg: Orange, film-coated, round, with "NRS" debossed on one side and "025" on the other side 1 mg: Orange, film-coated, rectangle, with "NRS" debossed on one side and "1" on the other side	Each carton contains 6 weekly blister cards containing the following total number of tablets: • Week 1 (ten x 0.25 mg tablets) • Week 2 (fourteen x 0.25 mg tablets and two x 1 mg tablets) • Week 3 (nine x 0.25 mg tablets and eight x 1 mg tablets) • Week 4 (three x 0.25 mg tablets and eighteen x 1 mg tablets) • Week 5 (twenty-one x 1 mg tablets) • Week 6 (fifteen x 1 mg tablets)	0074-6090-40

16.2 Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) *[see USP Controlled Room Temperature]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Drug Interactions

Advise patients and/or caregivers to inform their healthcare provider of all the medicines the patient is taking, including over-the-counter medicines, dietary supplements, and herbal products (e.g., St. John's Wort), and if there is a change (e.g., discontinuing) in their medication *[see Dosage and Administration (2.2, 2.3), Drug Interactions (7.1, 7.2)]*. Instruct patients who are

initiating JUVMO when concomitantly taking a moderate CYP3A inducer how to properly administer the titration packs.

Hypotension/Orthostatic Hypotension

Advise patients that they may develop postural (orthostatic) hypotension with or without symptoms such as dizziness, nausea, falling, fainting, or blackouts, and sometimes sweating. Hypotension and/or orthostatic symptoms may occur more frequently during initial therapy or with an increase in dose at any time. Instruct patients to rise slowly after sitting or lying down while using JUVMO *[see Warnings and Precautions (5.1)]*.

Impulse Control/Compulsive Behaviors

Advise patients and their caregivers that patients may experience intense urges to spend money uncontrollably, intense urges to gamble, increased sexual urges, binge or compulsive eating, and/or other intense urges and the inability to control these urges while taking JUVMO alone or with one or more medication(s) for the treatment of Parkinson's disease. Advise patients that they should report any of these adverse reactions to their healthcare provider *[see Warnings and Precautions (5.2)]*.

Hallucinations/Psychotic Behavior

Inform patients that they may experience hallucinations (unreal visions, sounds, or sensations) and other symptoms of psychosis while taking JUVMO. Advise patients that they should report any of these adverse reactions to their healthcare provider *[see Warnings and Precautions (5.3)]*.

Dyskinesia

Inform patients that JUVMO may cause or exacerbate pre-existing dyskinesias *[see Warnings and Precautions (5.4)]*.

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20104412

PATIENT INFORMATION
JUVMO™ (joov'-moh)
(tavapadon)
tablets, for oral use

What is JUVMO?

JUVMO is a prescription medicine used for the treatment of Parkinson's disease (PD) in adults.

It is not known if JUVMO is safe and effective in children.

Before taking JUVMO, tell your healthcare provider about all your medical conditions, including if you:

- have low blood pressure (hypotension), or if your blood pressure decreases when standing (orthostatic hypotension).
- have or have had unusual urges such as problems with gambling, compulsive eating, compulsive shopping, and increased sex drive.
- have a mental health problem, such as psychosis.
- have seen or have been seeing things that are not there, hearing sounds, or feeling sensations that are not real (hallucinations).
- have trouble controlling your muscles (dyskinesia).
- are pregnant or plan to become pregnant. It is not known if JUVMO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if JUVMO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take JUVMO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicine, vitamins, and herbal supplements.

JUVMO and certain other medicines may affect each other and how they work.

Know the medicines you take. Keep a list of them and show your healthcare provider and pharmacist when you get a new medicine.

How should I take JUVMO?

- Take JUVMO exactly as your healthcare provider tells you to.
- Your healthcare provider may change your dose if needed.
- Take JUVMO by mouth with or without food.
- If you miss a dose of JUVMO, take it as soon as you remember on the same day, but do not take 2 doses at one time. If you do not remember until the following day, skip the missed dose and take JUVMO at your regular time.
- If you take too much JUVMO, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking JUVMO?

- Do not change your body position too fast. Get up slowly from sitting or lying down. JUVMO can lower your blood pressure, which can cause nausea, sweating, dizziness, falling, or fainting when you stand up too quickly.

What are the possible side effects of JUVMO?

JUVMO may cause serious side effects, including:

- **low blood pressure. This is a common side effect and may be serious.** JUVMO can lower your blood pressure and make you feel dizzy, especially when you stand up (orthostatic hypotension). To help avoid this, do not get up

too fast from sitting or after lying down. You may be more likely to feel dizzy after starting JUVMO or when your dose is increased.

- **unusual urges.** Some people taking certain medicines to treat PD, including JUVMO, have had unusual urges. This may include gambling, compulsive eating, compulsive shopping, and increased sex drive. If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.
- **seeing things that are not there, hearing sounds, or feeling sensations that are not real (hallucinations). This is a common side effect and may be serious.** Hallucinations can happen in people who use JUVMO. Tell your healthcare provider if you have hallucinations.
- **uncontrolled sudden movements (dyskinesia). This is a common side effect and may be serious.** If you have new dyskinesia, or your dyskinesia gets worse, tell your healthcare provider. This may be a sign that your dose of JUVMO or other medicines to control your PD may need to be adjusted.

The most common side effects of JUVMO include:

- nausea
- headache
- change in taste
- feeling tired (fatigue)
- vomiting
- dry mouth
- anxiety

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of JUVMO. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store JUVMO?

- Store JUVMO at room temperature between 68°F to 77°F (20°C to 25°C).

Keep JUVMO and all medicines out of the reach of children.

General information about the safe and effective use of JUVMO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use JUVMO for a condition for which it was not prescribed. Do not give JUVMO to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about JUVMO that is written for health professionals.

What are the ingredients in JUVMO?

Active ingredient: tavapadon

Inactive ingredients:

0.25 mg and 1 mg tablets contain: lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, red iron oxide, sodium starch glycolate, talc, titanium dioxide, and yellow iron oxide.

5 mg, 10 mg, and 15 mg tablets contain: carmine, FD&C Blue No. 2, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, talc and titanium dioxide.

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For more information, call 1-888-817-4847 or go to www.JUVMO.com.

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