Aduhelm®
(aducanumab-avwa)

100 mg/mL
injection, for
intravenous use

ADUHELM Dosing & Administration Guide

Please see Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

Biogen

Actor Portrayal

Aduhelm®
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INDICATION

ADUHELM is indicated for the treatment of Alzheimer's disease. Treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including ADUHELM, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages, some of which have been fatal, have been observed in patients treated with this class of medications.

ApoE ε4 Homozygotes

Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including ADUHELM, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed they can still be treated with ADUHELM; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.

Consider the benefit of ADUHELM for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with ADUHELM.

Pre-Infusion Counseling

ADUHELM Medication Guide

Confirm the referring physician has provided the patient with the **ADUHELM Medication Guide**. Allow for the opportunity to answer questions.

Hypersensitivity reactions

Hypersensitivity reactions, including angioedema and urticaria, were reported in one patient during the placebo-controlled period of Studies 1 and 2, and occurred during the ADUHELM infusion.

Promptly discontinue ADUHELM upon the first observation of any symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy.[1]

Other medications

Ask about all other medications the patient may be taking, including over-the-counter medicines, vitamins, and herbal supplements.

It is especially important to ask about medications that reduce blood clots (antithrombotic medicines, including aspirin).[1]

Duration of infusion

Inform the patient that the infusion will take **approximately 1 hour**.[1] Let the patient know that you will be observing them throughout that time, but they are free to read a book or use their tablet or phone, if allowed.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Amyloid Related Imaging Abnormalities

- Monoclonal antibodies directed against aggregated forms of beta amyloid, including ADUHELM, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and ARIA with hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H of any cause and ARIA-E can occur together

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

- ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. When present, reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time. The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes. In addition to ARIA, intracerebral hemorrhages greater than 1 cm in diameter have occurred in patients treated with ADUHELM
- Consider the benefit of ADUHELM for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with ADUHELM

Incidence of ARIA

- Symptomatic ARIA occurred in 10% (110/1105) of patients treated with ADUHELM in Studies 1 and 2. Serious symptoms associated with ARIA were reported in 0.3% of patients treated with ADUHELM. Clinical symptoms associated with ARIA resolved in 88% of patients during the period of observation. Overall, recurrent episodes of ARIA-E were less frequently symptomatic (12%) compared with initial episodes of ARIA-E (25%)
- Including asymptomatic radiographic events, ARIA was observed in 41% (454/1105) of patients treated with ADUHELM 10 mg/kg compared to 10% (111/1087) of patients on placebo in Studies 1 and 2. ARIA-E was observed in 35% (387/1105) of patients treated with ADUHELM 10 mg/kg compared with 3% (29/1087) of patients on placebo. ARIA-H was observed in 28% (312/1105) of patients treated with ADUHELM compared to 9% (94/1087) of patients on placebo. There was no increase in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) for ADUHELM compared to placebo
- The overall incidence of seizure, independent of ARIA, was 0.5% in the 10 mg/kg ADUHELM group and 0.8% in the placebo group in Studies 1 and 2. In patients with ARIA in the 10 mg/kg ADUHELM group, the incidence of seizure was 0.7%. Status epilepticus was reported in the placebo-controlled and long-term extension studies in patients treated with ADUHELM

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

ApoE ε4 Carrier Status and Risk of ARIA

- Approximately 15% of Alzheimer's disease patients are ApoE ε4 homozygotes. In Studies 1 and 2, among patients with a known ApoE ε4 genotype, 17% (182/1103) of patients in the ADUHELM group were ApoE ε4 homozygotes, 51% (564/1103) were heterozygotes, and 32% (357/1103) were noncarriers. The incidence of symptomatic ARIA was higher in ApoE ε4 homozygotes (16%) than in heterozygotes (11%) and noncarriers (5%) among patients treated with ADUHELM. However, the incidence of serious adverse reactions with ARIA-E, including risk of death, persistent or significant disability or incapacity, hospitalization, or other medically important event that may require intervention to prevent serious outcomes, was similar for ApoE ε4 carriers and noncarriers (2% in homozygotes, 1% in heterozygotes, 2% in noncarriers)
- The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed they can still be treated with ADUHELM; however, it cannot be determined if they are ApoE ε4 homozygotes and at a higher risk for ARIA. An FDA-authorized test for detection of ApoE ε4 alleles to identify patients at risk of ARIA if treated with ADUHELM is not currently available. Currently available tests used to identify ApoE ε4 alleles may vary in accuracy and design

Radiographic Findings

- The radiographic severity of ARIA associated with ADUHELM was classified by radiographic criteria. **Mild ARIA-E:** FLAIR hyperintensity confined to sulcus and or cortex/subcortical white matter in one location < 5 cm. **Moderate ARIA-E:** FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring < 10 cm. **Severe ARIA-E:** FLAIR hyperintensity measuring > 10 cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted. **Mild ARIA-H microhemorrhage:** ≤ 4 new incident microhemorrhages. **Moderate ARIA-H microhemorrhage:** 5 to 9 new incident microhemorrhages. **Severe ARIA-H microhemorrhage:** 10 or more new incident microhemorrhages. **Mild ARIA-H superficial siderosis:** 1 focal area of superficial siderosis. **Moderate ARIA-H superficial siderosis:** 2 focal areas of superficial siderosis. **Severe ARIA-H superficial siderosis:** > 2 focal areas of superficial siderosis

How ADUHELM Is Supplied

ADUHELM injection is a preservative-free, sterile, clear to opalescent, and colorless to yellow solution.[1] ADUHELM is supplied one vial per carton as follows:

170 mg/1.7 mL
(100 mg/mL) single-dose vial
with red flip cap

300 mg/3 mL
(100 mg/mL) single-dose vial
with blue flip cap

Vials and packages not actual size.

Storage and Handling

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for intravenous use

Unopened vial[1]

- Store in a refrigerator at 2-8°C (36-46°F), in the original carton, until use.
- Do not freeze or shake.
- Protect from light.
- If no refrigeration is available, ADUHELM may be stored unopened in its original carton, protected from light at or below 25°C (77°F) for up to 3 days.
- Prior to dilution, unopened vials of ADUHELM may be removed from and returned to the refrigerator if necessary. Total combined time out of refrigeration and exposure to light should not exceed 24 hours at room temperature up to 25°C (77°F).

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

Radiographic Findings (cont'd)

- The majority of ARIA-E radiographic events occurred early in treatment (within the first 8 doses), although ARIA can occur at any time and patients can have more than 1 episode. The maximum radiographic severity of ARIA-E in patients treated with ADUHELM was mild in 10% (115/1105) of patients, moderate in 20% (223/1105) of patients, and severe in 4% (49/1105) of patients. Resolution on MRI occurred in 68% of ARIA-E patients by 12 weeks, 91% by 20 weeks, and 98% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with ADUHELM was mild in 14% (154/1105) of patients, moderate in 3% (29/1105) of patients, and severe in 3% (29/1105) patients. The maximum radiographic severity of ARIA-H superficial siderosis in patients treated with ADUHELM was mild in 7% (79/1105) of patients, moderate in 4% (47/1105) of patients, and severe in 3% (36/1105) of patients. Among patients treated with ADUHELM, the incidence of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes 11% (20/182), compared to heterozygotes 4% (21/564) or noncarriers 2% (8/357). Among patients treated with ADUHELM, the incidence of severe radiographic ARIA-H (microhemorrhage and superficial siderosis) was highest in ApoE ε4 homozygotes 20% (36/182), compared to heterozygotes 4% (21/564) or noncarriers 2% (6/357)

Please see Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

Dosing and Monitoring

Before treatment initiation with ADUHELM[1]

- Confirm the presence of Aβ pathology prior to initiating treatment
- Obtain a recent brain MRI prior to initiating treatment

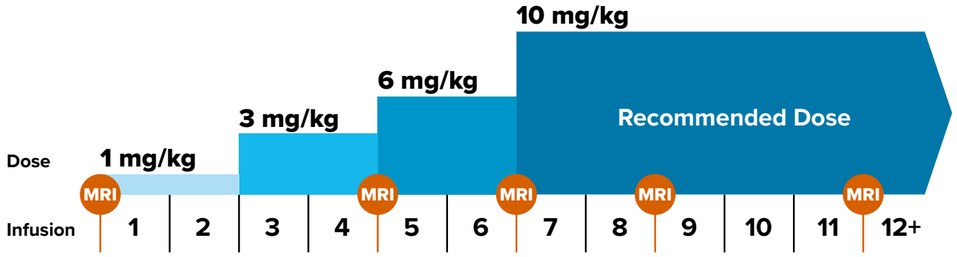
Recommended dose: After an initial titration, the recommended dosage of ADUHELM is 10 mg/kg[1]

- ADUHELM must be titrated slowly as indicated in the dosing schedule
- ADUHELM must be diluted and is administered as an intravenous infusion every 4 weeks. If an infusion is missed, resume administration at the same dose as soon as possible and at least 21 days apart

Obtaining brain MRIs[1]

- Obtain a recent brain MRI prior to initiating treatment with ADUHELM
- Obtain MRIs prior to the 5th infusion (first 6 mg/kg dose), 7th infusion (first 10 mg/kg dose), 9th infusion (third 10 mg/kg dose), and 12th infusion (sixth 10 mg/kg dose)

Titration and monitoring schedule[1]



This graphic depicts an example titration schedule based on the standard dosing schedule. Individual patient treatment may vary.

- Enhanced clinical vigilance for ARIA is recommended for the first 8 doses of treatment with ADUHELM, particularly during titration
- If a patient experiences symptoms suggestive of ARIA, perform a clinical evaluation, including MRI, if indicated
- If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

Intracerebral Hemorrhage

- Intracerebral hemorrhage greater than 1 cm in diameter was reported in 0.5% (6/1105) of patients in Studies 1 and 2 after treatment with ADUHELM compared to 0.4% (4/1087) of patients on placebo. Fatal events of intracerebral hemorrhage in patients taking ADUHELM have been observed

Concomitant Antithrombotic Medication

- Patients who received ADUHELM and an antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) did not have an increased risk of ARIA-H or intracerebral hemorrhage compared to patients who received placebo and an antithrombotic medication. The majority of exposures to antithrombotic medications were to aspirin; few patients were exposed to other antiplatelet drugs or anticoagulants, limiting any meaningful conclusions about the risk of ARIA or intracerebral hemorrhage in patients taking other antiplatelet drugs or anticoagulants

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

Concomitant Antithrombotic Medication (cont'd)

- Because intracerebral hemorrhages greater than 1 cm in diameter have been observed in patients taking ADUHELM, additional caution should be exercised when considering the administration of anticoagulants or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with ADUHELM

Other Risk Factors for Intracerebral Hemorrhage

- Patients were excluded from enrollment in Studies 1 and 2 for findings on neuroimaging that indicated an increased risk for intracerebral hemorrhage. These included findings suggestive of cerebral amyloid angiopathy (prior intracerebral hemorrhage greater than 1 cm in diameter, more than 4 microhemorrhages, superficial siderosis, and history of diffuse white matter disease). Vasogenic edema could also be suggestive of cerebral amyloid angiopathy. These and other lesions (aneurysm, vascular malformation) could potentially increase the risk of intracerebral hemorrhage

Aβ=amyloid beta; ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; MRI=magnetic resonance imaging.

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Dose Interruptions for ARIA

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Recommendations for dosing interruptions in patients with ARIA[1]

- If dosing is resumed following a temporary suspension, dosing may resume at that same dose and titration schedule prior to the dosing suspension

Dosing Recommendations for Patients with ARIA-E

Clinical Symptom Severity*	ARIA-E Severity on MRI‡		
	MILD	MODERATE	SEVERE
ASYMPTOMATIC	May continue dosing at current dose and schedule	Suspend dosing†	Suspend dosing†
MILD	May continue dosing based on clinical judgment	Suspend dosing†	
MODERATE OR SEVERE	Suspend dosing†		

*Mild: discomfort noticed, but no disruption of normal daily activity.
Moderate: discomfort sufficient to reduce or affect normal daily activity.
Severe: incapacitating, with inability to work or to perform normal daily activity.
†Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.
‡See Table 4 in the Prescribing Information, ARIA MRI Classification Criteria.

Dosing Recommendations for Patients with ARIA-H

Clinical Symptom Severity	ARIA-H Severity on MRI¶		
	MILD	MODERATE	SEVERE
ASYMPTOMATIC	May continue dosing at current dose and schedule	Suspend dosing§	Suspend dosing‖
SYMPTOMATIC	Suspend dosing§	Suspend dosing§	

§Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.
‖Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment in considering whether to continue treatment or permanently discontinue ADUHELM.
¶See Table 4 in the Prescribing Information, ARIA MRI Classification Criteria.

- In patients who develop intracerebral hemorrhage >1 cm in diameter during treatment with ADUHELM, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve
  - In Studies 1 and 2, dosing was permanently discontinued for patients who developed intracerebral hemorrhage >1 cm in diameter
  - Use clinical judgment in considering whether to continue treatment after radiographic stabilization and resolution of symptoms or permanently discontinue

The benefits of reaching and maintaining the 10 mg/kg dose should be considered when evaluating a potential dose suspension[1]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

Other Risk Factors for Intracerebral Hemorrhage (cont'd)

- The presence of an ApoE ε4 allele is also associated with cerebral amyloid angiopathy which has an increased risk for intracerebral hemorrhage
- Caution should be exercised when considering the use of ADUHELM in patients with factors that indicate an increased risk for intracerebral hemorrhage and in particular for patients who need to be on anticoagulant therapy

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

Monitoring and Dose Management Guidelines

- Recommendations for dosing in patients with ARIA-E depend on clinical symptoms and radiographic severity. Recommendations for dosing in patients with ARIA-H depend on the type of ARIA-H and radiographic severity. Use clinical judgment in considering whether to continue dosing in patients with recurrent ARIA-E

Please see Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

Sample Dosing Table[2]

Weight (lb/kg)		Infusions 1 & 2 (Starting Dose)	Infusions 3 & 4	Infusions 5 & 6	Infusions 7 + (Recommended dose after titration)
lb	kg	1 mg/kg	3 mg/kg	6 mg/kg	10 mg/kg
155	70.3	70.3	210.9	421.8	703
156	70.8	70.8	212.4	424.8	708
157	71.2	71.2	213.6	427.2	712
158	71.7	71.7	215.1	430.2	717
159	72.1	72.1	216.3	432.6	721
160	72.6	72.6	217.8	435.6	726
161	73	73	219	438	730
162	73.5	73.5	220.5	441	735
163	73.9	73.9	221.7	443.4	739
164	74.4	74.4	223.2	446.4	744
165	74.8	74.8	224.4	448.8	748
166	75.3	75.3	225.9	451.8	753
167	75.7	75.7	227.1	454.2	757
168	76.2	76.2	228.6	457.2	762
169	76.7	76.7	230.1	460.2	767
170	77.1	77.1	231.3	462.6	771
171	77.6	77.6	232.8	465.6	776
172	78	78	234	468	780
173	78.5	78.5	235.5	471	785
174	78.9	78.9	236.7	473.4	789

Weight (lb/kg)		Infusions 1 & 2 (Starting Dose)	Infusions 3 & 4	Infusions 5 & 6	Infusions 7 + (Recommended dose after titration)
lb	kg	1 mg/kg	3 mg/kg	6 mg/kg	10 mg/kg
175	79.4	79.4	238.2	476.4	794
176	79.8	79.8	239.4	478.8	798
177	80.3	80.3	240.9	481.8	803
178	80.7	80.7	242.1	484.2	807
179	81.2	81.2	243.6	487.2	812
180	81.6	81.6	244.8	489.6	816
181	82.1	82.1	246.3	492.6	821
182	82.6	82.6	247.8	495.6	826
183	83	83	249	498	830
184	83.5	83.5	250.5	501	835
185	83.9	83.9	251.7	503.4	839
186	84.4	84.4	253.2	506.4	844

This sample dosing table is provided as is for use by healthcare professionals and is not a substitute for clinical judgment. All calculations should be confirmed before use. See full Prescribing Information for additional dosing information. Biogen, and other parties involved in the preparation or publication of this brochure, is not liable for decisions made in reliance of this information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

Monitoring and Dose Management Guidelines (cont'd)

- Baseline brain MRI and periodic monitoring with MRI are recommended. Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment
- There is limited experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic moderate or severe ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E

How to Prepare ADUHELM Solution for Use[1]

Prior to administration, ADUHELM must be diluted in 100 mL of 0.9% Sodium Chloride Injection, USP. Use aseptic technique when preparing the ADUHELM diluted solution for intravenous infusion.

Calculate

- Calculate the dose, the total volume of ADUHELM solution required, and the number of vials needed based on the patient's actual body weight
- Each vial contains an ADUHELM concentration of 100 mg per mL

Inspect Vial

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Check that the ADUHELM solution is clear to opalescent and colorless to yellow solution
- Do not use if opaque particles, discoloration, or other foreign particles are present

Dilute

- Remove the flip-off cap from the vial
- Insert syringe needle into the vial through the center of the rubber stopper
- Withdraw the required volume from the vial(s) and add to an infusion bag of 100 mL of 0.9% Sodium Chloride Injection, USP. Do not use other intravenous diluents to prepare the diluted solution
- Each vial is for single dose only. Discard any unused portion
- Gently invert the infusion bag containing the ADUHELM diluted solution to mix completely. Do not shake
- After dilution, immediate use is recommended. If not administered immediately, store the diluted solution of ADUHELM in 0.9% Sodium Chloride Injection, USP refrigerated at 2°C to 8°C (36°F to 46°F) for up to 3 days, or at room temperature up to 30°C (86°F) for up to 12 hours. Do not freeze

How to Infuse ADUHELM[1]

Inspect Solution

- Visually inspect ADUHELM diluted solution for particles or discoloration prior to administration
- Do not use if it is discolored, opaque, or foreign particles are seen

Infuse

- Prior to infusion, allow the ADUHELM diluted solution to warm to room temperature
- Infuse ADUHELM diluted solution intravenously over approximately 1 hour through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter

Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity-type reaction.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions

- Angioedema and urticaria were reported in one patient in the placebo-controlled period of Studies 1 and 2, and occurred during the ADUHELM infusion. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy

ADVERSE REACTIONS

- In the combined placebo-controlled and long-term extension periods, 5% (66 out of 1386) of patients in the 10 mg/kg dose group withdrew from the study because of an adverse reaction. The most common adverse reaction resulting in study withdrawal in the combined placebo-controlled and long-term extension periods was ARIA-H superficial siderosis
- The most common adverse reactions reported in at least 2% of patients treated with ADUHELM 10 mg/kg and at least 2% more frequently than in patients on placebo in Studies 1 and 2 were ARIA-E, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, fall, diarrhea, and confusion/delirium/altered mental status/disorientation

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Actor Portrayal

Patient Counseling

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Inform patients and caregivers that ADUHELM may cause ARIA. ARIA most commonly presents as temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain. Inform patients that most people with swelling in areas of the brain do not experience symptoms, however, some people may experience symptoms such as headache, confusion, dizziness, vision changes, nausea, aphasia, weakness, or seizure.[1]

Instruct patients to notify their healthcare provider if these symptoms occur or any other symptoms.

Inform patients that events of intracerebral hemorrhage greater than 1 cm in diameter have been reported infrequently in patients taking ADUHELM, and that the use of anticoagulant or thrombolytic medications while taking ADUHELM may increase the risk of bleeding in the brain.[1]

Notify patients that their healthcare provider will perform MRI scans to monitor for ARIA.

Inform patients that although ARIA can occur in any patient treated with ADUHELM, there is an increased risk in patients who are ApoE ε4 homozygotes, and that testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Inform patients that if testing is not performed, it cannot be determined if they are ApoE ε4 homozygotes and at a higher risk for ARIA.[1]

Patient Registry: Advise patients that the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) is a voluntary provider-enrolled patient registry that collects information on treatments for Alzheimer's disease, including ADUHELM. Encourage patients to participate in the ALZ-NET registry.

Be aware of **hypersensitivity reactions**, which may include angioedema or urticaria.[1]

Schedule the **next infusion appointment**. Schedule an **MRI** prior to the next infusion if clinically indicated.

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References: 1. ADUHELM Prescribing Information. Cambridge, MA: Biogen; August 2023. **2.** Biogen. Data on file.

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