

Where
there's
ADCETRIS
there's

Hope

Oncology/Haematology Unit

← Reception

← Transplant Centre

← Pharmacy

→ Way Out

Your pocket guide to administering
ADCETRIS[®]

brentuximab vedotin

Key information for healthcare professionals on the administration of ADCETRIS. For a full overview of ADCETRIS, including contraindications, warnings and precautions for use and adverse events, please refer to the SmPC.

Prescribing information for ADCETRIS (brentuximab vedotin) and adverse event reporting can be found at the end of this pocket guide.

This pocket guide has been fully funded and developed by Takeda and is intended for healthcare professionals working in Ireland only.



ONCOLOGY

Indications

ADCETRIS is indicated for the treatment of adult patients with:

- Previously untreated CD30+ **Stage III or IV Hodgkin lymphoma (HL)** in combination with doxorubicin, vinblastine and dacarbazine (AVD)*
- Previously untreated CD30+ **Stage IIB with risk factors, Stage III or Stage IV HL** in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD)*
- Relapsed or refractory (R/R) CD30+ **HL** following:
 - autologous stem cell transplant (ASCT)[†] **or**
 - at least 2 prior therapies when ASCT or multi-agent chemotherapy is not a treatment option[†]
- CD30+ **HL** at increased risk of relapse or progression following ASCT[†]
- CD30+ **cutaneous T-cell lymphoma (CTCL)** after at least 1 prior systemic therapy[†]
- Previously untreated **systemic anaplastic large cell lymphoma (sALCL)**, in combination with cyclophosphamide, doxorubicin and prednisone (CHP)[†]
- R/R **sALCL**[†]

* A pharmacoeconomic assessment for this indication has not been completed

[†] Please visit NCCP website for information on the above approved regimens for ADCETRIS use in Ireland

Recommended dosing for ADCETRIS (monotherapy)

Adult patients with **R/R HL, HL** at increased risk of relapse or progression following **ASCT, R/R CTCL or R/R sALCL**

1.8 mg/kg intravenous infusion over 30 minutes every 3 weeks

Retreatment of adult patients with **R/R HL or R/R sALCL**, who have previously responded to treatment with ADCETRIS

1.8 mg/kg intravenous infusion over 30 minutes every 3 weeks
Or last tolerated dose

Adult patients with **hepatic impairment or severe renal impairment receiving ADCETRIS monotherapy***

1.2 mg/kg intravenous infusion over 30 minutes every 3 weeks

Patients **aged 65 and over**

Same dosing recommendations as for adults

If the patient's weight is more than 100 kg, the dose calculation should use 100 kg.

Number of cycles

- Number of cycles is dependent on response
- Patients with **R/R HL or R/R sALCL** who achieve stable disease or better should receive a minimum of **8 cycles** and up to a maximum of **16 cycles**
- For patients with **HL** at increased risk of relapse or progression following ASCT, ADCETRIS treatment should start following recovery from ASCT based on clinical judgment. These patients should receive up to **16 cycles**
- Patients with **R/R CTCL** should receive up to **16 cycles**

* These patients should be closely monitored for adverse events

Recommended dosing for ADCETRIS (combination therapy)

Combination with AVD^{*†}

Adult patients with **previously untreated CD30+ Stage III or IV HL** in combination with AVD

1.2 mg/kg intravenous infusion over 30 minutes on days 1 and 15 of each 28 day cycle

Adult patients with **mild hepatic impairment** receiving ADCETRIS in combination with AVD[‡]

0.9 mg/kg intravenous infusion over 30 minutes every 2 weeks

Patients **aged 65 and over** receiving ADCETRIS in combination with AVD

Same dosing recommendations as for adults

If the patient's weight is more than 100 kg, the dose calculation should use 100 kg.

Primary prophylaxis with growth factor support (G-CSF) beginning with the first dose is recommended for all adult patients receiving ADCETRIS combination therapy with AVD.

Avoid use of ADCETRIS in combination with chemotherapy in:

- **Moderate and severe hepatic impairment[§]**
- **Severe renal impairment[¶]**

* Refer to the Summary of Product Characteristics for chemotherapy agents given in combination with ADCETRIS

† A pharmacoeconomic assessment for this indication has not been completed

‡ These patients should be closely monitored for adverse events

§ There is no clinical trial experience using ADCETRIS in combination with chemotherapy in patients with hepatic impairment, where total bilirubin is $>1.5 \times$ upper limit of normal (ULN) (unless due to Gilbert syndrome), or aspartate aminotransferase or alanine aminotransferase are $>3 \times$ ULN, or $>5 \times$ ULN if their elevation may be reasonably ascribed to the presence of HL in the liver

¶ There is no clinical trial experience using ADCETRIS in combination with chemotherapy in patients with renal impairment, where serum creatinine is ≥ 2.0 mg/dL and/or creatinine clearance or calculated creatinine clearance is ≤ 40 mL/minute

Recommended dosing for ADCETRIS (combination therapy)

Combination with CHP*

Adult patients with **previously untreated sALCL** in combination with CHP

1.8 mg/kg intravenous infusion over 30 minutes every 3 weeks

Adult patients with **mild hepatic impairment** receiving ADCETRIS in combination with CHP[†]

1.2 mg/kg intravenous infusion over 30 minutes every 3 weeks

Patients **aged 65 and over** receiving ADCETRIS in combination with CHP

Same dosing recommendations as for adults

If the patient's weight is more than 100 kg, the dose calculation should use 100 kg.

Primary prophylaxis with growth factor support (G-CSF) beginning with the first dose is recommended for all adult patients receiving ADCETRIS combination therapy with CHP.

Avoid use of ADCETRIS in combination with chemotherapy in:

- **Moderate and severe hepatic impairment^{†‡}**
- **Severe renal impairment^{†§}**

* Refer to the Summary of Product Characteristics for chemotherapy agents given in combination with ADCETRIS

[†] These patients should be closely monitored for adverse events

[‡] There is no clinical trial experience using ADCETRIS in combination with chemotherapy in patients with hepatic impairment, where total bilirubin is $>1.5 \times$ upper limit of normal (ULN) (unless due to Gilbert syndrome), or aspartate aminotransferase or alanine aminotransferase are $>3 \times$ ULN, or $>5 \times$ ULN if their elevation may be reasonably ascribed to the presence of HL in the liver

[§] There is no clinical trial experience using ADCETRIS in combination with chemotherapy in patients with renal impairment, where serum creatinine is ≥ 2.0 mg/dL and/or creatinine clearance or calculated creatinine clearance is ≤ 40 mL/minute

Combination with ECADD*†

Adult patients with **CD30+ Stage IIB with risk factors, Stage III or Stage IV HL**

1.8 mg/kg intravenous infusion over 30 minutes every 3 weeks

Patients aged **60 and over** receiving ADCETRIS in combination with ECADD

The safety and efficacy has not been established in this patient population

If the patient's weight is more than 100 kg, the dose calculation should use 100 kg.

Primary prophylaxis with G-CSF must be given beginning on day 5 of each cycle for all adult patients with previously untreated HL receiving ADCETRIS combination therapy with ECADD. Pretreatment with dexamethasone for 4 days before the first cycle of chemotherapy is recommended for patients >40 years of age or at physician's discretion. An antibiotic prophylaxis must be given 3 x/week during the whole duration of chemotherapy.

Avoid use of ADCETRIS in combination with chemotherapy in:

- **Moderate and severe hepatic impairment*§**
- **Severe renal impairment†¶**

Number of cycles

- Number of cycles is dependent on response
- Patients with **previously untreated CD30+ Stage III or IV HL** should receive **6 cycles** in combination with AVD*
- Patients with **previously untreated sALCL** should receive **6 to 8 cycles** in combination with CHP*
- Patients with **previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL** should receive up to **6 cycles** with BrECADD*

* Refer to the Summary of Product Characteristics for chemotherapy agents given in combination with ADCETRIS

† A pharmacoeconomic assessment for this indication has not been completed

‡ These patients should be closely monitored for adverse events

§ There is no clinical trial experience using ADCETRIS in combination with chemotherapy in patients with hepatic impairment, where total bilirubin is >1.5 x upper limit of normal (ULN) (unless due to Gilbert syndrome), or aspartate aminotransferase or alanine aminotransferase are >3 x ULN, or >5 x ULN if their elevation may be reasonably ascribed to the presence of HL in the liver

¶ There is no clinical trial experience using ADCETRIS in combination with chemotherapy in patients with renal impairment, where serum creatinine is ≥2.0 mg/dL and/or creatinine clearance or calculated creatinine clearance is ≤40 mL/minute

Dose calculation

Step 1:

Calculate the total ADCETRIS dose (ml) to be further diluted:

$$\frac{\text{ADCETRIS dose (mg/kg)} \times \text{Patient's body weight (kg)}}{\text{Reconstituted vial concentration (5 mg/ml)}}$$

For patients >100 kg, use 100 kg in the calculation

Step 2:

Determine the total number of ADCETRIS vials needed:

$$\frac{\text{Total ADCETRIS dose (ml) to be administered}}{\text{Total volume per vial (10 ml/vial)}} = \text{Number of ADCETRIS vials needed}$$

Sample calculations for patients receiving the recommended dose of 1.8 mg/kg, 1.2 mg/kg and 0.9 mg/kg of ADCETRIS for weights ranging from 60–120kg:

Recommended dose	Patient weight	Total dose	Total volume to be diluted	Number of vials needed
1.8 mg/kg	60 kg	108 kg	21.6 ml	2.16 vials
	80 kg	144 kg	28.8 ml	2.88 vials
	100 kg	180 kg	36 ml	3.6 vials
	120 kg*	180 kg†	36 ml	3.6 vials
1.2 mg/kg	60 kg	72 mg	14.4 ml	1.44 vials
	80 kg	96 mg	19.2 ml	1.92 vials
	100 kg	120 mg‡	24 ml	2.4 vials
	120 kg*	120 mg‡	24 ml	2.4 vials
0.9 mg/kg	60 kg	54 mg	10.8 ml	1.08 vials
	80 kg	72 mg	14.4 ml	1.44 vials
	100 kg	90 mg§	18 ml	1.8 vials
	120 kg*	90 mg§	18 ml	1.8 vials

* For patients >100 kg, use 100 kg in the calculation

† The maximal recommended dose is 180 mg

‡ The maximal recommended dose is 120 mg

§ The maximal recommended dose is 90 mg

Dose adjustments

Dosing recommendations for neutropenia

If neutropenia develops during treatment it should be managed by dose delays or dose adjustments in subsequent cycles, as outlined below.

Monotherapy (R/R HL, consolidation in HL post-ASCT, R/R CTCL and R/R sALCL)

Severity grade of neutropenia (signs and symptoms [abbreviated description of CTCAE*])	Modification of dosing schedule
Grade 1 (<LLN–1,500/mm ³ <LLN–1.5 x 10 ⁹ /L) or Grade 2 (<1,500–1,000/mm ³ <1.5–1.0 x 10 ⁹ /L)	Continue with the same dose and schedule
Grade 3 (<1,000–500/mm ³ <1.0–0.5 x 10 ⁹ /L) or Grade 4 (<500/mm ³ <0.5 x 10 ⁹ /L)	Withhold dose until toxicity returns to ≤Grade 2 or baseline then resume treatment at the same dose and schedule.† Consider growth factor support (G-CSF or GM-CSF) in subsequent cycles for patients who develop Grade 3 or Grade 4 neutropenia

AVD/CHP combination therapy (previously untreated CD30+ Stage III or IV HL, previously untreated sALCL)

Severity grade of neutropenia (signs and symptoms [abbreviated description of CTCAE‡])	Modification of dosing schedule
Grade 1 (<LLN–1,500/mm ³ <LLN–1.5 x 10 ⁹ /L) or Grade 2 (<1,500–1,000/mm ³ <1.5–1.0 x 10 ⁹ /L) Grade 3 (<1,000–500/mm ³ <1.0–0.5 x 10 ⁹ /L) or Grade 4 (<500/mm ³ <0.5 x 10 ⁹ /L)	Primary prophylaxis with G-CSF, beginning with the first dose, is recommended for all patients receiving combination therapy. Continue with the same dose and schedule

* Grading based on National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.0; see neutrophils/granulocytes; LLN = lower limit of normal
† Patients who develop Grade 3 or Grade 4 lymphopenia may continue treatment without interruption
‡ Grading based on NCI CTCAE v3.0

BrECADD combination therapy (previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL)*

Dosing recommendations for brentuximab vedotin for haematotoxicities during therapy.

Severity grade (signs and symptoms [abbreviated description of CTCAE†])	Modification of dosing schedule
Leukocytes ($\geq 2,500/\text{mm}^3$ $\geq 2.5 \times 10^9/\text{L}$) OR Neutrophils ($\geq 1,500/\text{mm}^3$ $\geq 1.5 \times 10^9/\text{L}$) AND Thrombocytes $\geq 80,000/\text{mm}^3$ $\geq 80 \times 10^9/\text{L}$	Continue with the same dose and schedule
Leukocytes ($< 2,000\text{--}1,000/\text{mm}^3$ $< 2.0\text{--}1.0 \times 10^9/\text{L}$) OR Neutrophils ($< 1,000\text{--}500/\text{mm}^3$ $< 1.0\text{--}0.5 \times 10^9/\text{L}$) AND Thrombocytes ($< 50,000\text{--}25,000/\text{mm}^3$ $< 50.0\text{--}25.0 \times 10^9/\text{L}$)	Withhold treatment until toxicity returns to baseline; if the events do not recover by day 28 of the cycle, a dose reduction of brentuximab vedotin 1.2 mg/kg up to a maximum of 120 mg every 3 weeks can be considered
Leukocytes ($< 1,000/\text{mm}^3$ $< 1.0 \times 10^9/\text{L}$) OR Neutrophils ($< 500/\text{mm}^3$ $< 0.5 \times 10^9/\text{L}$) AND Thrombocytes ($< 25,000/\text{mm}^3$ $< 25.0 \times 10^9/\text{L}$)	Withhold treatment until toxicity returns to baseline then resume brentuximab vedotin treatment with a reduced dose of 1.2 mg/kg up to a maximum of 120 mg every 3 weeks

* A pharmacoeconomic assessment for this indication has not been completed

† Grading based on National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.0; see neutrophils/granulocytes; LLN = lower limit of normal

Starting dose and dose reduction levels for BrECADD treatment

Dose level	Cyclophosphamide (C)	Doxorubicin (A)	Etoposide (E)	Dacarbazine (D)	Dexamethasone (D)
4 (starting dose)	1,250 mg/m ²	40 mg/m ²	150 mg/m ²	250 mg/m ²	40 mg
3	1,100 mg/m ²	40 mg/m ²	125 mg/m ²	250 mg/m ²	40 mg
2	950 mg/m ²	40 mg/m ²	100 mg/m ²	250 mg/m ²	40 mg
1	800 mg/m ²	40 mg/m ²	100 mg/m ²	250 mg/m ²	40 mg
Baseline (lowest dose)	650 mg/m ²	35 mg/m ²	100 mg/m ²	250 mg/m ²	40 mg

- If one or more events occur in a given cycle the dose should be reduced to the level below and continued for the next cycles*
- If events occur in two successive cycles the dose should be reduced to baseline level*

Refer to the table above for details of dosing levels

* Events include leukopenia for more than 4 days, thrombocytopenia on 1 or more days, infection CTCAE Grade 4, other CTCAE grade 4 toxicities, and treatment delay of more than 2 weeks due to inadequate recovery of blood values

Dosing recommendations for new or worsening peripheral sensory or motor neuropathy

If peripheral sensory or motor neuropathy emerges or worsens during treatment, follow the appropriate dosing recommendations below.

Monotherapy (R/R HL; consolidation in HL post-ASCT; R/R CTCL and R/R sALCL)

Severity grade of peripheral sensory or motor neuropathy (signs and symptoms [abbreviated description of CTCAE*])	Modification of dosing schedule (monotherapy)
Grade 1 (paraesthesia and/or loss of reflexes, with no loss of function)	Continue with the same dose and schedule
Grade 2 (interfering with function but not with activities of daily living) or Grade 3 (interfering with activities of daily living)	Withhold dose until toxicity returns to ≤Grade 1 or baseline, then restart treatment at a reduced dose of 1.2 mg/kg every 3 weeks up to a maximum of 120 mg
Grade 4 (sensory neuropathy which is disabling or motor neuropathy that is life threatening or leads to paralysis)	Discontinue treatment

* Grading based on National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v3.0; see neuropathy: motor; neuropathy: sensory; and neuropathic pain

BrECADD/CHP/AVD combination therapy (previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL; previously untreated CD30+ Stage III or IV HL; previously untreated sALCL)

Severity of peripheral sensory or motor neuropathy (signs and symptoms [abbreviated description of CTCAE*])	Modification of dosing schedule (combination with CHP)	Modification of dosing schedule (combination with AVD†)	Modification of dosing schedule (combination with ECADD†)
Grade 1 (paraesthesia and/ or loss of reflexes, with no loss of function)	Continue with the same dose and schedule	Continue with the same dose and schedule	Continue with the same dose and schedule
Grade 2 (interfering with function but not with activities of daily living)	Sensory neuropathy: Continue treatment at same dose level. Motor neuropathy: Reduce dose to 1.2 mg/kg, up to a maximum of 120 mg every 3 weeks	Reduce dose to 0.9 mg/kg up to a maximum of 90 mg every 2 weeks	Withhold treatment until symptoms have subsided to ≤Grade 1 level or initial state, then restart ADCETRIS treatment at a reduced dose of 1.2 mg/kg up to a maximum of 120 mg every 3 weeks
Grade 3 (interfering with activities of daily living)	Sensory neuropathy: Reduce dose to 1.2 mg/kg up to a maximum of 120 mg every 3 weeks Motor neuropathy: Discontinue treatment	Withhold treatment with ADCETRIS until toxicity is ≤Grade 2, then restart treatment at a reduced dose to 0.9 mg/kg up to a maximum of 90 mg every 2 weeks	
Grade 4 (sensory neuropathy which is disabling or motor neuropathy that is life threatening or leads to paralysis)	Discontinue treatment	Discontinue treatment	Discontinue treatment

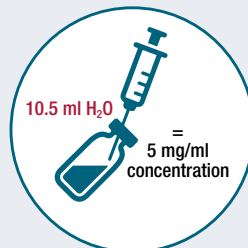
* Grading based on National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03; see neuropathy: motor; neuropathy: sensory; and neuropathic pain

† A pharmacoeconomic assessment for this indication has not been completed

Reconstitution

1. Reconstitute each single use vial with **10.5 ml** of water for injection to a final concentration of **5 mg/ml**.

Direct the stream to the wall of the vial and not directly at the powder



2. Gently swirl the vial to aid dissolution.

Do not shake

The reconstituted solution in the vial is a clear to slightly opalescent, colourless solution



3. Visually inspect the reconstituted solution for any foreign particles and/or discolouration.

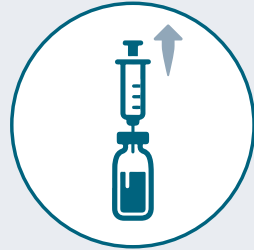
Discard if you observe any particles or discolouration



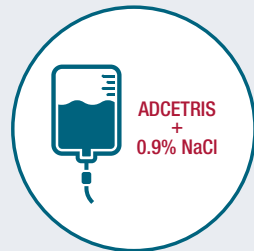
Aseptic technique should be followed throughout the handling of ADCETRIS

Preparation of infusion solution

1. Withdraw the calculated amount of reconstituted ADCETRIS from vials



2. Add to an infusion bag containing **sodium chloride 9 mg/ml (0.9%)** solution for injection for a **final concentration of 0.4–1.2 mg/ml** of ADCETRIS



3. The recommended diluent volume is **150 ml**. The already reconstituted ADCETRIS can also be diluted into **5% dextrose** for injection or **Lactated Ringer's** for injection



Administering ADCETRIS



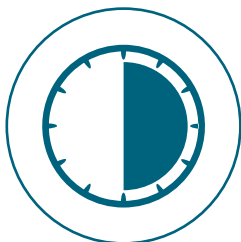
Monitor complete blood counts before dosing



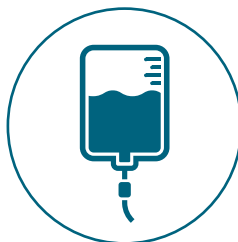
DO NOT give as IV push or bolus

**Gently invert the prepared infusion bag to mix
DO NOT SHAKE**

- **Do not** add other medicinal products to the prepared ADCETRIS infusion solution or intravenous infusion set
- **The infusion line should be flushed** following administration with sodium chloride 9 mg/ml (0.9%), 5% dextrose for injection, or Lactated Ringer's for injection
- Following dilution, the ADCETRIS solution should be infused **immediately**



Infuse over 30 minutes



Through a dedicated IV line

Storage

- Keep vial in original carton to protect from light and store in refrigerator (2–8°C)
- Do not freeze
- Chemical and in-use stability of reconstituted/diluted product has been demonstrated for 24 hours at 2–8°C

Infusion-related reactions

Infusion-related reactions are very common (affecting more than 1 in 10 people) for monotherapy and common (affecting more than 1 in 100 people but less than 1 in 10 people) for combination therapy. They may be **immediate or delayed**.

- Anaphylactic reactions have been reported
- Infusion-related reactions are more **frequent and severe** in patients with antibodies to ADCETRIS
- Patients should be **carefully monitored** during and after infusion for signs of these reactions
- Infusion-related reactions include:



Rash



Back pain



Shortness of breath



Chills



Difficulty breathing



Headache



Cough



Fever



A tight chest



Feeling sick (nausea)
or being sick (vomiting)



Infusion site pain



Itching

What to do if your patient experiences an infusion-related reaction

If an infusion-related reaction occurs, treatment should be interrupted and appropriate medical management instituted.

- The infusion may be restarted at a **slower rate** after symptom resolution
- Patients who have experienced a prior infusion-related reaction should be **premedicated** for subsequent infusions. Premedication may include paracetamol, an antihistamine and a corticosteroid



If an anaphylactic reaction occurs, ADCETRIS should be immediately and permanently discontinued and appropriate medical therapy should be administered.

Symptoms of an anaphylactic reaction may include, but are not limited to, urticaria, angioedema, hypotension and bronchospasm

For more information on ADCETRIS adverse events please refer to the Summary of Product Characteristics.

Reference:

ADCETRIS Summary of Product Characteristics. February 2026.

ADCTETRIS® (brentuximab vedotin) PRESCRIBING INFORMATION FOR REPUBLIC OF IRELAND

Refer to Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each vial contains 50 mg brentuximab vedotin powder for concentrate for solution for infusion. **Indications:** Treatment of adult patients as follows: **Monotherapy:** CD30+ Hodgkin lymphoma (HL) at increased risk of relapse or progression following autologous stem cell transplant (ASCT); relapsed or refractory (R/R) CD30+ HL following ASCT, or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option; R/R systemic anaplastic large cell lymphoma (sALCL); CD30+ cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy. **Combination therapy:** ADCTETRIS in combination with doxorubicin, vinblastine and dacarbazine (AVD) in previously untreated CD30+ Stage III or IV HL. ADCTETRIS in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine and dexamethasone (BrEACAD) in previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL. ADCTETRIS in combination with cyclophosphamide, doxorubicin and prednisone (CHP) in previously untreated sALCL. **Dosage and administration:** ADCTETRIS should be administered under the supervision of a physician experienced in the use of anti-cancer agents. Administer ADCTETRIS as an intravenous infusion over 30 minutes. Recommended doses are as follows: **Monotherapy:** HL at increased risk of relapse or progression: 1.8 mg/kg every 3 weeks for up to 16 cycles following recovery from ASCT; R/R HL and R/R sALCL: 1.8 mg/kg every 3 weeks; same dose and schedule is recommended for retreatment of patients who previously responded to ADCTETRIS or start at the last tolerated dose. Patients achieving stable disease or better should receive a minimum of 8 cycles and up to a maximum of 16 cycles (approximately 1 year). Treat until disease progression or unacceptable toxicity. CTCL: 1.8 mg/kg every 3 weeks up to 16 cycles. **Combination therapy:** Refer to the SmPCs of chemotherapy agents given in combination with ADCTETRIS. Previously untreated HL (AVD): ADCTETRIS dose with AVD is 1.2 mg/kg on days 1 and 15 of each 28-day cycle for 6 cycles. Primary prophylaxis with growth factor support (G-CSF) beginning with first dose is recommended for all adult patients. Previously untreated HL (BrEACAD): ADCTETRIS dose with BrEACAD is 1.8 mg/kg every 3 weeks for up to 6 cycles. Primary prophylaxis with G-CSF must be given beginning on day 5 of each cycle for all adult patients. Pretreatment with dexamethasone for 4 days before first cycle is recommended for patients > 40 years of age or at physician's discretion. Antibiotic prophylaxis must be given 3 weeks during whole duration of chemotherapy. Previously untreated sALCL: ADCTETRIS dose with CHP is 1.8 mg/kg every 3 weeks for 6 to 8 cycles. Primary prophylaxis with G-CSF beginning with first dose is recommended for all adult patients. **General:** If patient's weight is more than 100 kg, dose calculation should be using 100 kg. Monitor complete blood counts prior to administration of each dose and monitor patients during and after infusion. **Dose adjustments:** Refer to SmPC for full dose modifications. **Peripheral sensory/motor neuropathy:** If peripheral sensory or motor neuropathy emerges or worsens during treatment, patients may require dose delay and reduction or discontinuation of ADCTETRIS (≥Grade 2). **Neutropenia:** **Monotherapy:** If Grade 3 or 4 neutropenia develops, manage by dose delays and consider use of G-CSF. Continue with same dose and schedule for Grade 1 or 2 neutropenia. **Combination therapy:** For all Grades with AVD/CHP, if neutropenia develops, continue with same dose and schedule. For haematotoxicities during BrEACAD combination therapy manage by dose delays or dose adjustment in subsequent cycles. If one or more events occur in a given cycle, dose is reduced to the level below and continued for next cycles. If events occur in two successive cycles, the dose is reduced to baseline level. Refer to SmPC for details of dose levels and full dosing recommendations. **Renal and hepatic impairment:** Closely monitor patients for adverse events. Recommended starting doses are as follows: **Monotherapy:** 1.2 mg/kg every 3 weeks in patients with hepatic impairment or severe renal impairment. **Combination therapy:** Avoid use in patients with moderate and severe hepatic impairment or severe renal impairment. **Mild hepatic impairment:** Previously untreated HL: 0.9 mg/kg every 2 weeks in combination with AVD; Previously untreated sALCL: 1.2 mg/kg every 3 weeks in combination with CHP. **Elderly patients (≥65 years):** Dose same as for adults. Safety and efficacy of ADCTETRIS dose with BrEACAD has not been established in patients ≥ 60 years. **Monotherapy:** May be more susceptible to events such as pneumonia, neutropenia and febrile neutropenia. **Combination therapy:** More serious adverse events and dose modifications were reported in older patients compared with the overall study population. Advanced age was a risk factor for febrile neutropenia. **Paediatric patients (<18 years):** Safety and efficacy has not been established. **Method of administration:** ADCTETRIS requires reconstitution and dilution before administration – refer to SmPC. Infuse ADCTETRIS over 30 minutes. Must not be administered as an intravenous push or bolus. Administer ADCTETRIS through a dedicated intravenous line and do not mix with other medicinal products. **Contraindications:** Hypersensitivity to active substance or excipients. Combined use of bleomycin and ADCTETRIS causes pulmonary toxicity. **Warnings and precautions:** **Progressive multifocal leukoencephalopathy (PML):** John Cunningham virus reactivation resulting in PML and death can occur in ADCTETRIS-treated patients. PML has been reported in patients who received ADCTETRIS after receiving multiple prior chemotherapy regimens. Monitor patients closely for new or worsening neurological, cognitive, or behavioural signs or symptoms, which may be suggestive of PML. Withhold ADCTETRIS dosing for any suspected case of PML and permanently discontinue if diagnosis of PML is confirmed. **Pancreatitis:** Acute pancreatitis has been observed and fatal outcomes reported. Monitor patients for abdominal pain suggestive of acute pancreatitis. Withhold dosing if acute pancreatitis is suspected and discontinue if a diagnosis is confirmed. **Pulmonary toxicity:** Cases of pulmonary toxicity including pneumonitis, interstitial lung disease, and acute respiratory distress syndrome, some with fatal outcomes, have been reported. In event of new or worsening pulmonary symptoms, a prompt diagnostic evaluation is required and patients treated appropriately. Consider holding ADCTETRIS dosing during evaluation and until symptomatic improvement. **Serious infections and opportunistic infections:** Serious infections such as pneumonia, staphylococcal bacteraemia, sepsis/septic shock (including fatal outcomes) and herpes zoster, cytomegalovirus (reactivation) and opportunistic infections such as Pneumocystis jiroveci pneumonia (PJP) and oral candidiasis have been reported in patients treated with ADCTETRIS. Monitor patients carefully during treatment. **Infusion-related reactions (IRR):** Immediate and delayed IRRs, as well as anaphylactic reactions, have been reported (more frequently and severely in patients with antibodies to ADCTETRIS). Monitor patients during and after infusion. ADCTETRIS should be immediately and permanently discontinued if anaphylactic reaction occurs. Infusion should be interrupted if IRR occurs and appropriate management instituted. Infusion may be restarted at a slower rate after resolution. Use premedication for subsequent infusions in instances of prior IRR. **Tumour lysis syndrome (TLS):** Patients with rapidly proliferating tumour and high tumour burden are at risk of TLS; monitor these patients and manage according to best medical practice. **Peripheral neuropathy:** ADCTETRIS may cause peripheral neuropathy which is reversible in most cases. Monitor patients for symptoms of neuropathy. Patients experiencing new or worsening peripheral neuropathy may require delay or dose reduction or discontinuation of ADCTETRIS. Refer to SmPC for dose adjustments if peripheral neuropathy develops. **Haematological toxicities:** Grade 3 or 4 anaemia, thrombocytopenia and prolonged (≥ 1 week) Grade 3 or 4 neutropenia can occur with ADCTETRIS. Refer to SmPC for dose adjustments if neutropenia develops. **Febrile neutropenia:** Has been reported with ADCTETRIS. Monitor patients for fever and manage according to best medical practice if febrile neutropenia develops. When ADCTETRIS was administered in combination with AVD, CHP or as the

BrEACAD regimen, advanced age was a risk factor for febrile neutropenia; With AVD/CHP, primary prophylaxis with G-CSF beginning with the first dose is recommended for all adult patients regardless of age. As part of the BrEACAD regimen, primary prophylaxis with G-CSF must be given beginning on day 5 of each cycle for all adult patients regardless of age. **Severe cutaneous adverse reactions (SCARs):** Cases of SCARs, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with ADCTETRIS. Fatal outcomes have been reported for SJS and TEN. If SJS, TEN or DRESS occur, discontinue ADCTETRIS treatment and administer appropriate medical therapy. **Gastrointestinal (GI) complications:** GI complications including intestinal obstruction, ileus, enterocolitis, neutropenic colitis, erosion, ulcer, perforation and haemorrhage, some with fatal outcomes, have been reported. In event of new or worsening GI symptoms, perform a prompt diagnostic evaluation and treat appropriately. **Hepatotoxicity:** Elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) have been reported. Serious cases of hepatotoxicity, including fatal outcomes, have also occurred. Test liver function before initiating treatment and routinely monitor in patients receiving ADCTETRIS. Patients experiencing hepatotoxicity may require a delay, change in dose or discontinuation of ADCTETRIS. **Hyperglycaemia:** Any patient who experiences an event of hyperglycaemia should have their serum glucose closely monitored and anti-diabetic treatment administered as appropriate. **Infusion site extravasation:** Extravasation during intravenous infusion has occurred therefore it is recommended to closely monitor the infusion site for possible infiltration during drug administration. **Renal and hepatic impairment:** Monomethyl auristatin E (MMAE) clearance might be affected by severe renal impairment, hepatic impairment, and by low serum albumin concentrations. **CD30+ CTCL:** Size of treatment effect in CD30+ CTCL subtypes other than mycosis fungoides and primary cutaneous anaplastic large cell lymphoma is not clear due to lack of high level evidence. Use ADCTETRIS with caution in other CD30+ CTCL subtypes after consideration of the potential benefit-risk. **Sodium content in excipients:** ADCTETRIS contains 13.2 mg sodium per vial. **Polysorbate 80 content in excipients:** ADCTETRIS contains 2 mg polysorbate 80 per vial. Polysorbates may cause allergic reactions. **Traceability:** In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. **Interactions:** Co-administration of ADCTETRIS with strong CYP3A4 and P-gp inhibitors, such as ketoconazole, may increase the incidence of neutropenia; with rifampicin, a strong CYP3A4 inducer, did not alter the plasma exposure to ADCTETRIS, however, it appeared to reduce plasma concentrations of MMAE metabolites. ADCTETRIS is not expected to alter the exposure to medicines that are metabolised by CYP3A4 enzymes e.g. midazolam. Co-administration of ADCTETRIS is not expected to affect the exposure of AVD or CHP. Co-administration of ADCTETRIS with bleomycin is contraindicated. Exposures of ADCTETRIS and concurrent chemotherapy are not expected to be affected in the BrEACAD regimen. **Fertility, pregnancy and lactation:** Women of childbearing potential should use two methods of effective contraception during treatment with ADCTETRIS and until 6 months after treatment. There are no data in pregnant women. Animal studies have shown reproductive toxicity. ADCTETRIS should not be used during pregnancy unless benefit to mother outweighs potential risks to foetus. There are no data as to whether ADCTETRIS or its metabolites are excreted in human milk. A risk to the newborn/infant cannot be excluded. In non-clinical studies, ADCTETRIS treatment has resulted in testicular toxicity, and may alter male fertility. Men being treated with ADCTETRIS are advised not to father a child during treatment and for up to 6 months following the last dose. **Effects on ability to drive and use machines:** ADCTETRIS may have a moderate influence on the ability to drive and use machines. **Undesirable effects (all grades):** **Monotherapy: Very common (≥1/10):** In the pooled dataset of ADCTETRIS as monotherapy across HL, sALCL and CTCL studies, the most frequent adverse reactions (≥10%) were infections, peripheral sensory neuropathy, nausea, fatigue, diarrhoea, pyrexia, neutropenia, upper respiratory tract infection, arthralgia, rash, cough, vomiting, pruritus, peripheral motor neuropathy, infusion-related reactions, constipation, dyspnoea, myalgia, weight decreased, abdominal pain. **Monotherapy: Common (≥1/100 to <1/10):** Herpes zoster, pneumonia, herpes simplex, oral candidiasis, anaemia, thrombocytopenia, hyperglycaemia, dizziness, ALT/AST increased, alopecia, back pain, chills. **Monotherapy: Serious adverse reactions:** Herpes zoster, pneumonia, pneumocystis jiroveci pneumonia, staphylococcal bacteraemia, cytomegalovirus infection or reactivation, sepsis/septic shock, neutropenia, anaemia, thrombocytopenia, febrile neutropenia, anaphylactic reaction, tumour lysis syndrome, peripheral sensory neuropathy, peripheral motor neuropathy, demyelinating polyneuropathy, pancreatitis acute, Stevens-Johnson syndrome/toxic epidermal necrolysis, progressive multifocal leukoencephalopathy, drug reaction with eosinophilia and systemic symptoms. **Combination therapy (AVD/CHP): Very common (≥1/10):** In the studies of ADCTETRIS as combination therapy in 662 patients with previously untreated advanced HL and 223 patients with previously untreated CD30+ peripheral T-cell lymphoma, the most common adverse reactions (≥10%) were: infections, neutropenia, peripheral sensory neuropathy, nausea, constipation, vomiting, diarrhoea, fatigue, pyrexia, alopecia, anaemia, weight decreased, stomatitis, febrile neutropenia, abdominal pain, decreased appetite, insomnia bone pain, rash, cough, dyspnoea, arthralgia, myalgia, back pain, peripheral motor neuropathy, upper respiratory tract infection, dizziness. **Combination therapy (AVD/CHP): Common (≥1/100 to <1/10):** Pneumonia, oral candidiasis, sepsis/septic shock, herpes zoster, thrombocytopenia, hyperglycaemia, ALT/AST increased, pruritus, infusion-related reactions, chills. **Combination therapy (AVD/CHP): Serious adverse reactions:** Serious adverse reactions occurring in ≥3% of patients included febrile neutropenia (15%), pyrexia (5%), and neutropenia (3%). Other serious adverse reactions included pneumonia, herpes simplex, Pneumocystis jiroveci pneumonia, anaemia, thrombocytopenia, anaphylactic reaction, tumour lysis syndrome, peripheral sensory neuropathy, peripheral motor neuropathy, pancreatitis acute, Stevens-Johnson syndrome. **Combination therapy (BrEACAD regimen):** In the HD21 study, the safety profile of ADCTETRIS in 747 patients receiving BrEACAD remained consistent with other combination therapy (AVD/CHP). **Combination therapy (BrEACAD regimen): Serious adverse reactions:** Serious adverse reactions occurring in >3% of patients were febrile neutropenia (19.3%), pyrexia (3.9%), and neutropenia (3.2%). Other serious adverse reactions/events included tachycardia and cardiac failure. Refer to the SmPC for details on full side effect profile and interactions. **Legal classification:** POM. **Marketing authorisation (MA) number:** EU/1/12/794/001. **Name and address of MA holder:** Takeda Pharma A/S, Delta Park 45, 2665 Vallensbæk Strand, Denmark. Additional information is available on request at: medinfoema@takeda.com. **PI approval code:** pi-03703. **Date of preparation:** June 2025.

Adverse events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority. Reporting forms and information can be found at: www.hpra.ie. Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com



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