For healthcare professionals in the United Kingdom only.
Prescribing Information can be found via the links at the bottom of this page.

KEYTRUDA SC®

(pembrolizumab)
subcutaneous injection

395 mg/2.4 mL
790 mg/4.8 mL



DOSING, STORAGE & ADMINISTRATION GUIDE

Actor portrayal

KEYTRUDA SC is licensed for use across most **KEYTRUDA IV** indications, whether alone or in combination with other therapies.[1,2,3]

One such indication is: KEYTRUDA IV and KEYTRUDA SC, in combination with pemetrexed and platinum chemotherapy, are each indicated for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma in adults whose tumours have no *EGFR* or *ALK* positive mutations.[1,2,3]

Please consult the SmPCs and Risk Minimisation Materials for further information, including a full list of approved indications, before making prescribing decisions.

To access the full prescribing information please click the following links: **KEYTRUDA SC** 395 mg/2.4 mL **KEYTRUDA SC** 790 mg/4.8 mL **KEYTRUDA IV**

*These links will take you to a third party website**

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD (Tel: 020 8154 8000). This link will take you to a third party website.*

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MSD

MK-3475A-D77 study

KEYTRUDA SC was studied to evaluate PK non-inferiority to KEYTRUDA IV[4]

MK-3475A-D77 was a randomised, multicentre, open-label, active-controlled, Phase III, non-inferiority study comparing KEYTRUDA SC and KEYTRUDA IV, each in combination with chemotherapy for 1L mNSCLC patients across histologies and PD-L1 TPS expression status. 377 patients were randomised 2:1 between KEYTRUDA SC 790 mg Q6W and KEYTRUDA IV 400 mg Q6W.

Co-primary endpoints (non-inferiority of KEYTRUDA SC vs KEYTRUDA IV) based on:

- Cycle 1 $AUC_{0\text{-}6wks}$
- Steady state (cycle 3) C_{trough}

Secondary endpoints (based on descriptive analysis):

- ORR
- PFS
- OS
- Safety
- Immunogenicity

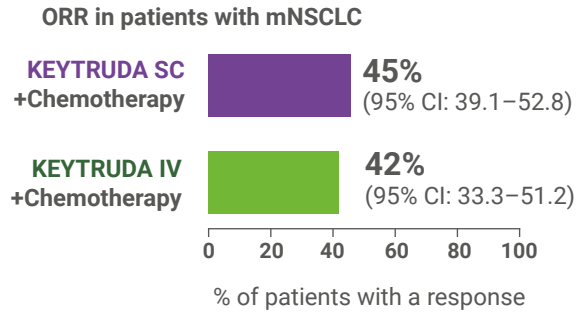
Pembrolizumab exposure of KEYTRUDA SC was non-inferior to KEYTRUDA IV

PK parameter	Geometric mean ratio
Cycle 1 $AUC_{0\text{-}6wks}$	**1.14** (96% CI: 1.06–1.22); p<0.0001
Cycle 3 (ie, steady state) C_{trough}	**1.67** (94% CI: 1.52–1.84); p<0.0001

The non-inferiority margin was prespecified as 0.8

Efficacy endpoints (PFS, ORR, OS) were comparable between KEYTRUDA SC and KEYTRUDA IV

Efficacy was a descriptive analysis and was not powered to demonstrate statistical significance



The safety profile of KEYTRUDA SC in combination with chemotherapy was consistent with the known safety profile of KEYTRUDA IV in combination with chemotherapy, with the addition of injection site reactions, which occurred in 2.4% (6/251) of patients receiving KEYTRUDA SC, all were Grade 1.

Any-Grade AEs: **KEYTRUDA SC** 99.2% vs **KEYTRUDA IV** 97.6%

Most common any-Grade AEs in KEYTRUDA SC arm:
anaemia (52.2%), neutropenia (41.8%), thrombocytopenia (28.3%)

Grades 3–5 AEs: **KEYTRUDA SC** 47.0% vs **KEYTRUDA IV** 47.6%

Most common Grades 3–5 AEs in KEYTRUDA SC arm:
anaemia (16.7%), neutropenia (21.5%), thrombocytopenia (10.0%)

The median time to onset of the first injection-site AEs from the most recent dose administration was 2.0 days (range 1–2 days); the median duration of the first event of injection-site AE was 5.5 days (range 2–20 days).

Product information and storage requirements

Two solution-strength vials are available for KEYTRUDA SC[1,2]

Active substance: pembrolizumab 395 mg/2.4 mL and pembrolizumab 790 mg/4.8 mL

Excipients: recombinant berahyaluronidase alfa, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, sucrose, polysorbate 80 (E433), water for injections

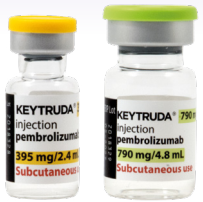
395 mg*/2.4 mL over 1 min Q3W

OR

790 mg*/4.8 mL over 2 mins Q6W

Storage of unopened vials[1,2]

KEYTRUDA SC has the same storage requirements as KEYTRUDA IV[1,2,3]



Vials shown to scale, not actual size.

- Store in a refrigerator (2°C–8°C)
- Store in the original carton to protect from light
- Do not shake or freeze vials

If removed from refrigeration, vials can remain at room temperature (≤25°C) for up to 24 hours before preparation for administration.

Storage of prepared syringes[1,2]

This product does not contain preservative and **should be used immediately after withdrawing from the vial**. If not used immediately, store the syringe containing KEYTRUDA SC with the **transfer needle and cap in place for:****



Up to 8 hours at room temperature

OR

Up to 24 hours† in the refrigerator (2°C–8°C)

If refrigerated, the filled syringe must be allowed to come to room temperature for at least 30 minutes prior to administration.

The syringe must not be frozen.

Do not attach the hypodermic needle until immediately prior to administration to avoid clogging.

Discard if storage time exceeds these limits

Do not store any unused portion of the solution for the injection for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

*Pembrolizumab; **In-use storage times and conditions prior to use are the responsibility of the user; †The 24-hour period may include up to 8 hours at room temperature.

Preparation of the injection syringe

The KEYTRUDA SC solution for injection can be prepared in four simple steps[1,2]

1 Check the vial

Check the vial label to ensure the correct formulation is prepared and administered to the patient as prescribed.

Visually inspect the vial for particulate matter and discolouration. The solution is clear to slightly opalescent, colourless to slightly yellow.

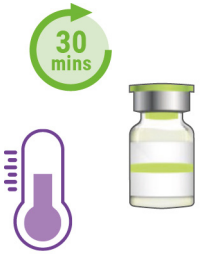


Discard the vial if visible particles or discolouration are observed.

2 Bring the vial to room temperature

Allow the refrigerated vial to come to room temperature for at least 30 minutes.

- Prior to the preparation for administration, if needed, the **unpunctured vial may be stored at room temperature for up to 24 hours**

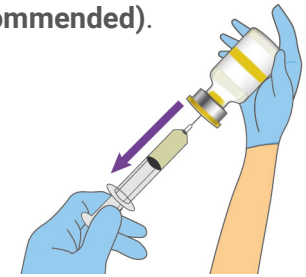


Do not dilute, do not shake the vial.

3 Withdraw the required volume

Withdraw either 2.4 mL (395 mg) or 4.8 mL (790 mg) using a sterile syringe and a **transfer needle (18–21G recommended)**.

- KEYTRUDA SC is compatible with polypropylene and polycarbonate syringe material and stainless-steel transfer and injection needles



KEYTRUDA SC vial is for single use only. Discard the empty vial or any unused portion left in the vial.*

4 Change to injection needle before use

To avoid needle clogging, change the needle to a 25–30G, 13 mm hypodermic injection needle immediately prior to subcutaneous injection.



Do not attach the hypodermic needle until immediately prior to administration to avoid clogging.



Disposal

- Vials are for single use only and any unused portion should be discarded
- Dispose in accordance with local requirements

*Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Administration

KEYTRUDA SC is administered over 1 or 2 minutes, with two subcutaneous injection-site options: the abdomen or thigh[1,2]

Should be administered by an HCP and must be administered by subcutaneous injection only:

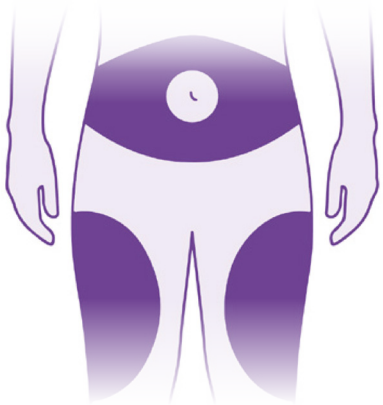
Q3W

Inject over
1 minute*
one dose
(395 mg/2.4 mL)

OR

Q6W

Inject over
2 minutes*
one dose
(790 mg/4.8 mL)



Administration techniques

- Inject into the subcutaneous tissue of the **thigh or abdomen**, avoiding the 5 cm area around the navel
- Do not inject into skin that is damaged, sore, bruised, scarred, scaly, or has red patches
- **Rotate injection sites** for subsequent injections (ensure the injection site is at least 2.5 cm from the previous injection site)
- During treatment with KEYTRUDA SC do not administer other medicinal products for subcutaneous use at the same site
- To best prepare for injection, consider recommending that your patients wear loose-fitting clothes, such as a skirt or shorts

For certain patients, treatment with KEYTRUDA SC could offer the opportunity for administration outside an infusion suite.[5]

*Does not account for all aspects of treatment. Actual clinic time may vary.

Dosing summary

KEYTRUDA SC provides two dosing options in a ready-to-use vial which doesn't require dilution (each with a distinct colour and ordering code)[1,2]

Dose: Q3W[1]

Administered subcutaneously over **1 minute***

Low injection volume: 2.4 mL

395 mg pembrolizumab

GTIN: 00366582512479
Carton: x1 vial, 50 mm x 50 mm x 90 mm



OR

Dose: Q6W[2]

Administered subcutaneously over **2 minutes***

Low injection volume: 4.8 mL

790 mg pembrolizumab

GTIN: 00366582512486
Carton: x1 vial, 50 mm x 50 mm x 90 mm

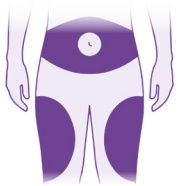


Vials shown to scale, not actual size.

Option to switch[1,2,3]

Patients have the option to switch from KEYTRUDA IV to KEYTRUDA SC – or from KEYTRUDA SC to KEYTRUDA IV – at their next scheduled dose

Two injection site options[1,2]



Thigh or abdomen, avoiding the 5 cm area around the navel

Faster administration vs KEYTRUDA IV[1,2,3]



KEYTRUDA SC | KEYTRUDA IV

KEYTRUDA SC can be administered over 1 or 2 minutes, providing faster administration than a 30-minute infusion of KEYTRUDA IV*

The approved adult indications for KEYTRUDA SC have been established based on the MK-3475A-D77 study, which demonstrated non-inferior pharmacokinetics, and provides a descriptive analysis for the efficacy and safety profile of KEYTRUDA SC compared to KEYTRUDA.[1,2]

The safety and efficacy of KEYTRUDA SC have not been established in paediatric patients, except for adolescents with melanoma or cHL aged 12 years and older who weigh more than 40 kg. For these adolescents, the recommended dose is the same as that for adults. The paediatric safety and efficacy profile of KEYTRUDA SC is based on extrapolation from intravenous pembrolizumab studies, as efficacy and safety in paediatric patients were not directly evaluated in the MK-3475A-D77 study.[1,2]

In addition, pharmacokinetic modelling and simulation analyses demonstrated similar pembrolizumab exposure in adolescents aged 12 years and older who weigh more than 40 kg compared with adults, suggesting a similar safety profile. Pembrolizumab exposures with subcutaneous doses of 395 mg every 3 weeks or 790 mg every 6 weeks in adolescents aged 12 years and older who weigh greater than 40 kg are expected to be an average of 30% higher to those of adult patients at the same dose, however this difference is not clinically meaningful.[1,2]

***Does not account for all aspects of treatment. Actual clinic time may vary.**

1L, first-line; AE, adverse event; AUC, area under the curve; *ALK*, anaplastic lymphoma kinase; C, concentration; cHL, classical Hodgkin lymphoma; CI, confidence interval; *EGFR*, epidermal growth factor receptor; GTIN, global trade item number; IV, intravenous; PK, pharmacokinetic; mNSCLC, metastatic non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death ligand-1; PFS, progression-free survival; Q3W, every three weeks; Q6W, every six weeks; SC, subcutaneous; TPS, tumour proportion score.

1. KEYTRUDA (pembrolizumab) 395 mg Solution for Injection Summary of Product Characteristics; **2.** KEYTRUDA (pembrolizumab) 790 mg Solution for Injection Summary of Product Characteristics; **3.** KEYTRUDA (pembrolizumab) 25 mg/mL Concentrate Solution for Infusion Summary of Product Characteristics; **4.** Felip E, *et al. Ann Oncol* 2025;36:775–785; **5.** De Cock E, *et al. Adv Ther.* 2025;42(12):6175–6189.