Note to Reviewers: The content is anchored to the Prescribing Information (PI) (uspi-mk3475-iv-2503r084) for KEYTRUDA of 19-MAR-2025, and to the draft PI for KEYTRUDA SubQ submitted in MK-3475A on 23-JAN-2025.

Note to Reviewers: The Select Safety Information (SSI) has not been approved for use. The SSI placeholder content is displayed throughout the submission in pink font color. FPO has been added over images that will be updated.

Dimensions:
8.5 inches x 11 inches

Note to Reviewers: The logo and generic name are still in development. This asset will not be deployed until the logo has been finalized and approved for use.

NOW APPROVED

KEYTRUDA QSub®

(genericnameabc/genericnameabc alfa-xxxx)

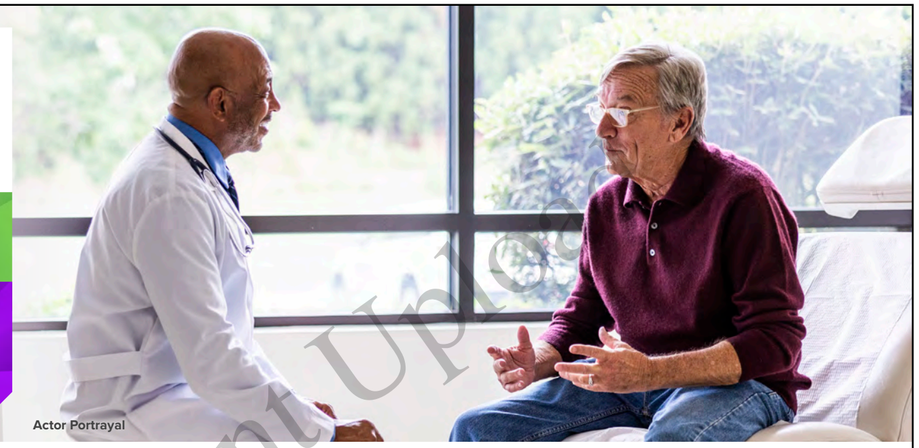
Injection for subcutaneous use / xxxxmg/xxxx units per mL

PROVEN CONSISTENCY WITH KEYTRUDA

ADMINISTERED SUBCUTANEOUSLY

IN ~1-2 MINUTES*

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



Actor Portrayal

KEYTRUDA QSUB is approved for use in adult patients across all solid tumor indications for KEYTRUDA—alone or in combination with other therapies

One such indication is: KEYTRUDA and KEYTRUDA QSUB are each indicated for the first-line treatment of patients with metastatic nonsquamous non–small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, in combination with pemetrexed and platinum chemotherapy.

The pharmacokinetic profile of KEYTRUDA QSUB has been demonstrated to be comparable to that of KEYTRUDA

- Cycle 1 $AUC_{0\text{-}6wks}$ showed non-inferiority of KEYTRUDA QSUB to KEYTRUDA, with a geometric mean ratio of 1.14 (96% CI: 1.06, 1.22)
- Cycle 3 C_{trough} (i.e., steady state) showed non-inferiority of KEYTRUDA QSUB to KEYTRUDA, with a geometric mean ratio of 1.67 (94% CI: 1.52, 1.84)

Links to the “KEYTRUDA QSUB non-inferiority study design (registrational study in 1L mNSCLC)” section within this submission.

View the Study Design

Flexible Q3W (2.4 mL) or Q6W (4.8mL) dosing with multiple injection site options

- **Q3W:** 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa administered in ~1 minute; **Q6W:** 790 mg pembrolizumab and 9,600 units berahyaluronidase alfa administered in ~2 minutes
- When administering KEYTRUDA QSUB to adult patients in combination with chemotherapy, administer KEYTRUDA QSUB prior to chemotherapy when given on the same day
- Treatment with KEYTRUDA QSUB should continue until disease progression, unacceptable toxicity, or up to 24 months

SELECTED SAFETY INFORMATION

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

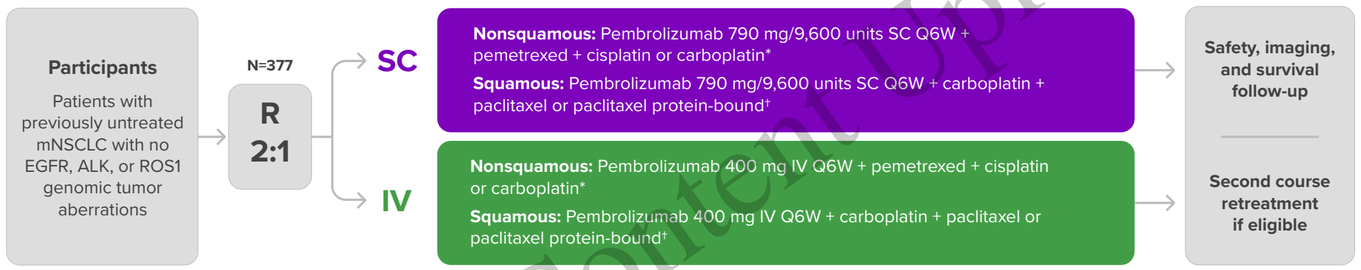
KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA QSub® (genericnameabc/genericnameabc alfa-xxxx) Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

KEYTRUDA QSUB was studied to evaluate its comparability to KEYTRUDA

In MK-3475A-D77, KEYTRUDA QSUB was evaluated in a randomized, multicenter, open-label, noninferiority study of the active-controlled pharmacokinetics, efficacy, and safety of KEYTRUDA QSUB in combination with chemotherapy vs KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with metastatic non-small cell lung cancer (mNSCLC).

KEYTRUDA QSUB non-inferiority study design (registrational study in 1L mNSCLC)



Primary Outcome Measures: $AUC_{0\text{-}6wks}$ [cycle 1] and C_{trough} at steady state

Descriptive Efficacy Outcome Measures: ORR, PFS, and OS

Chemotherapy Options

*Pemetrexed 500 mg/m^2 IV + cisplatin 75 mg/m^2 IV or carboplatin AUC 5 mg/ml/min IV Q3W for 4 cycles, followed by pemetrexed 500 mg/m^2 IV Q3W.

†Carboplatin AUC 6 mg/ml/min + paclitaxel 200 mg/m^2 IV on Day 1 of each 21-day cycle or paclitaxel protein-bound 100 mg/m^2 IV on Days 1, 8, and 15 of each 21-day cycle IV Q3W for 4 cycles.

1L = first-line; ALK = anaplastic lymphoma kinase; AUC (Area Under the Curve) = the total amount of the drug reaching the systemic circulation; C_{trough} (trough concentration) = highest concentration of drug in the blood; EGFR = epidermal growth factor receptor; IV = intravenous; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; PK = pharmacokinetics; ROS1 = ROS proto-oncogene 1, receptor tyrosine kinase; SC = subcutaneous; Q6W = every 6 weeks.

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

Calculation TPS <50%: 100% - 19% (TPS>/=50) = 81%

MK-3475A-D77: Patient baseline demographics and characteristics

Baseline Characterisitics	All Patients (N=377)
Median age, years (range)	65 (37-87)
Male sex	71%
Ethnicity/race	
White	63%
Hispanic or Latino	31%
Asian	29%
Multiracial	4%
Black	3%
American Indian	2%
ECOG PS	
0	35%
1	65%
PD-L1 expression	
TPS <50%	81%
TPS ≥50%	19%
Histology	
Nonsquamous	66%
Squamous	34%

ECOG PS = Eastern Cooperative Oncology Group Perfomance Status; PD-L1 = programmed death ligand 1; TPS = tumor progression score.

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

The comparability of KEYTRUDA QSUB and KEYTRUDA was established in Study MK-3475A-D77

Primary Outcome Measures:

Cycle 1 $AUC_{0\text{-}6wks}$
- GMR of 1.14 [96% CI, 1.06-1.22]

Steady State (Cycle 3) C_{trough}
- GMR of 1.67 [94% CI, 1.52-1.84]

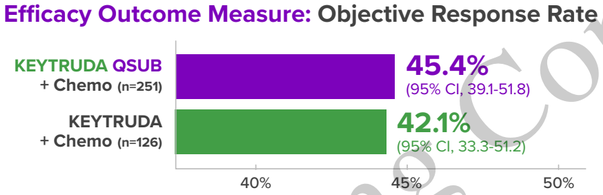
No clinically meaningful differences in the pharmacokinetics of KEYTRUDA QSUB and KEYTRUDA

- Use of KEYTRUDA QSUB for the approved indications is supported by evidence from adequate and well-controlled studies conducted with KEYTRUDA across tumor types and additional pharmacokinetic, efficacy, and safety data from MK-3475A-D77

Efficacy observed with KEYTRUDA QSUB was consistent with KEYTRUDA

Efficacy was a descriptive analysis and was not used to formally test for comparable efficacy to KEYTRUDA

Efficacy Outcome Measure: Objective Response Rate



Efficacy Outcome Measures:
Progression-Free Survival and Overall Survival

No notable differences in progression-free survival was observed when compared to KEYTRUDA.

At the time of analysis, overall survival results were not mature.

AUC (Area Under the Curve) = the total amount of the drug reaching the systemic circulation; CI = confidence interval; C_{trough} (trough concentration) = highest concentration of drug in the blood; GMR (Geometric Mean Ratio) = the ratio of the geometric mean of one group to the geometric mean of another group.

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

KEYTRUDA QSUB safety profile is consistent with the known safety profile of KEYTRUDA

Safety of KEYTRUDA QSUB across approved indications has been established in adequate and well controlled studies of KEYTRUDA QSUB and KEYTRUDA, as a single agent or in combination across tumor types.

The most common adverse reactions (≥20%) in patients treated with KEYTRUDA QSUB in combination with chemotherapy were anemia (59%), neutropenia (43%), leukopenia (30%), thrombocytopenia (29%), and nausea (25%).

- **Injection site reactions were 2.4% in patients receiving KEYTRUDA SUB and were all Grade 1 in nature**
- **Patient monitoring is the same as KEYTRUDA**

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

KEYTRUDA QSUB is designed to give your patients a flexible treatment experience

Administered in ~1-2 minutes*

~1 minute for 2.4 mL Q3W

~2 minutes for 4.8 mL Q6W

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

Two dosing options

Q3W: 395 mg pembrolizumab and 4,800 units/mL berahyaluronidase alfa.

Q6W: 790 mg pembrolizumab and 9,600 units/mL berahyaluronidase alfa.

Injection volume

2.4 mL Q3W or 4.8 mL Q6W

Multiple administration sites

Abdomen or thigh

- When administering KEYTRUDA QSUB to adult patients in combination with chemotherapy, administer KEYTRUDA QSUB prior to chemotherapy when given on the same day
- Treatment with KEYTRUDA QSUB should continue until disease progression, unnacceptable toxicity, or up to 24 months

For certain patients, KEYTRUDA QSUB may remove the need to be in an infusion chair, and may enable patients to receive treatment outside of the infusion suite

Patients have the option to switch from

KEYTRUDA → KEYTRUDA QSUB

or

KEYTRUDA QSUB → KEYTRUDA

at their next dose

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYTRUDA QSub® (genericnameabc/genericnameabc alfa-xxxx) Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

Storage of KEYTRUDA QSUB

Storing the vial

- Store vials under refrigeration at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light
- Do not shake or freeze vials

KEYTRUDA QSUB

Dose Q3W
Yellow cap

395 mg pembrolizumab and 4,800 units berahyaluronidase alfa per 2.4 mL (165 mg and 2,000 units per mL)

NDC 0006-3083-01

Dose Q6W
Light green cap

790 mg pembrolizumab and 9,600 units berahyaluronidase alfa per 2.4 mL (165 mg and 2,000 units per mL)

NDC 0006-5083-01

KEYTRUDA QSUB is a sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution supplied in single-dose vials for subcutaneous administration. Each carton contains one single-dose vial.

Vials shown to scale, not actual size.

KEYTRUDA

Dose Q3W & Q6W
Navy blue cap

Carton containing one 100 mg/4 mL (25 mg/mL), single-dose vial (NDC 0006-3026-02)

Carton containing two 100 mg/4 mL (25 mg/mL), single-dose vials (NDC 0006-3026-04)

KEYTRUDA QSUB has the same vial storage requirements as KEYTRUDA

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

Preparing and storing the syringe

Preparation of the syringe

- Equilibrate the vial of KEYTRUDA QSUB to room temperature for at least 30 minutes.
  - The unpunctured vial can be out of refrigeration for up to 24 hours prior to the preparation for administration.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution is clear to slightly opalescent, colorless to slightly yellow. Discard the vial is visible particles are observed.
- KEYTRUDA QSUB is compatible with polypropylene and polycarbonate syringe material and stainless-steel transfer and injection needles.
- Withdraw either 2.4 mL (395 mg/4,800 units) or 4.8 mL (790 mg/9,600 units) from the vial using a sterile syringe and a transfer needle (18-21 gauge recommended).
  - To avoid needle clogging, change the needle to a 25-30 gauge, ½-inch hypodermic injection needle immediately prior to subcutaneous injection

Storing the prepared syringe

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

- At room temperature for up to 8 hours, or
- Under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 24 hours. The 24-hour period may include up to 8 hours at room temperature.

Discard if storage time exceeds these limits.

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

Do not freeze.

KEYTRUDA QSUB offers a fixed dose with no reconstitution or IV line flush needed, which may save time in office

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

Give your patients a choice of where to receive their treatment

~1-2 minute subcutaneous administration*

one 2.4mL dose
every 3 weeks
over 1 minute

OR

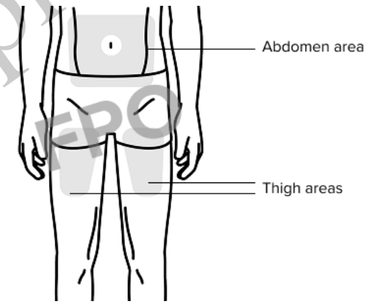
one 4.8mL dose
every 6 weeks
over 2 minutes

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

Two administration options: abdomen or upper thigh

KEYTRUDA QSUB can only be administered by a healthcare professional.

- Inject KEYTRUDA QSUB into the subcutaneous tissue of the thigh or abdomen, avoiding the 2-inch area around the navel. Do not inject into skin that is damaged, sore, bruised, scarred, scaly, or has red patches
- Rotate injection sites for successive injections
- During treatment with KEYTRUDA QSUB, do not administer other medications for subcutaneous use at the same site as KEYTRUDA QSUB
- Discard any unused portion left in the vial



SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA QSub®
(genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

The Merck Access Program

Scanning the QR code will open The Merck Access Program for KEYTRUDA Website on the user's mobile device.

The Merck Access Program may be able to help answer questions about:

- Benefit investigations
- Billing and coding
- Co-pay assistance for eligible patients
- The prior authorizations and appeals process
- Referral to the Merck Patient Assistance program for eligibility determination (provided through the Merck Patient Assistance Program, Inc.)
- Product distribution

For more information about access and support, scan the QR code or call 855-257-3932
(Monday–Friday, 8AM–8PM), or visit **merckaccessprogram-keytruda.com**

Caller will be directed to The Merck Access Program.

URL directs users to The Merck Access Program for KEYTRUDA Website.

SELECTED SAFETY INFORMATION *(CONTINUED)*

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Please see additional Important Safety Information throughout and US Full Prescribing Information for KEYTRUDA and KEYTRUDA QSUB.

KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA QSub® (genericnameabc/genericnameabc alfa-xxxx) Injection for subcutaneous use / xxxxmg/xxxx units per mL

Dimensions:
8.5 inches x 11 inches

Scanning the QR code will open the HCP QSUB landing page for KEYTRUDA on the user's mobile device.

Note to Reviewers: Website is being reviewed under US-PDS-00001.

URL will direct users to the HCP QSUB landing page for KEYTRUDA

Note to Reviewers: Website is being reviewed under US-PDS-00001.

KEYTRUDA QSUB: Subcutaneous treatment administered in ~1-2 minutes*

Broad

Approved for use in adult patients across all solid tumor indications for KEYTRUDA—alone or in combination with other therapies

Comparable

KEYTRUDA QSUB was shown to be comparable to KEYTRUDA in MK-3475A-D77

Flexible

Multiple dosing options and sites of administration

Scan the QR code with your phone or visit [vanity URL] to learn more about KEYTRUDA QSUB for your patients

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

SELECTED SAFETY INFORMATION *(CONTINUED)*

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References:

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KEYTRUDA QSub® (genericnameabc/genericnameabc alfa-xxxx)
Injection for subcutaneous use / xxxxmg/xxxx units per mL