Adakveo product ordering information brochure

Supplied and marketed by	Novartis Pharmaceuticals Corporation Internet: www.novartis.com www.ADAKVEO.com
Product name	ADAKVEO®
Established name	crizanlizumab-tmca
Indication	ADAKVEO® (crizanlizumab-tmca) is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients, aged 16 years and older, with sickle cell disease.[1]

Product information

NDC:	Description:	Sale pack quantity:
0078-0883-61	100 mg/10 mL (10 mg/mL) solution in a single-dose vial	1

Wholesale price

$2,357.14

Product availability

ADAKVEO will be available to ship on or about November 19, 2019.

All orders must be placed with a distributor listed below:

Authorized specialty distributors	Phone number	NDC number
ASD Specialty Healthcare	1-800-746-6273	0078-0883-61
Cardinal Health	1-866-677-4844	
McKesson Plasma and Biologics	1-877-625-2566	
McKesson Specialty Health	Oncology: 1-800-482-6700 Other specialties: 1-855-477-9800	

- Novartis does not recommend the use of any particular distributor
- ADAKVEO will be available for purchase by any licensed pharmacy
- ADAKVEO is also available through specialty pharmacies if preferred or required by your patient's health plan
- To assess whether a patient's insurance allows this medication to be accessed through a specialty pharmacy, please contact ADAKVEO Support at PANO at **1-800-282-7630** to speak with an insurance specialist or case manager

Dispensing pack dimensions

Depth: 4″ Height: 3″ Width: 1.75″

Storage and handling

- Store and transport refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light
- Do not shake. Do not freeze

Sales unit to trade

One single-dose vial

Product expiration

Expiration date printed on each sales unit

Please see pages 2–3 for Important Safety Information. Please click here for full Prescribing Information.

Prescription legend	Prescription only
How supplied	• ADAKVEO® (crizanlizumab-tmca) injection is a sterile, clear to opalescent, colorless to slightly brownish-yellow solution for intravenous infusion supplied in a carton containing one 100 mg/10 mL (10 mg/mL) solution in a single-dose vial. The single-dose vial has a rubber stopper and an aluminum cap with a plastic flip-off disk. Each 10 mL vial is made of Type 1 glass
Dose and volume calculation[1]	• Do not use if particles are present in the solution • Calculate the dose (mg) and the total volume (mL) of ADAKVEO solution required, and the number of ADAKVEO vials needed based on the patient's actual body weight **Total Volume** (mL) = **Patient body weight** (kg) x **5** mg/kg / **10** mg/mL of ADAKVEO **Number of Vials** = **Total Volume** (mL) / **10** mL/vial **Example:** An adult weighing 75 kg (165 lb) requires a volume of 37.5 mL or 3.75 vials of ADAKVEO (requires 4 vials) • Administer ADAKVEO 5 mg/kg by intravenous infusion over a period of 30 minutes at Week 0, Week 2, and every 4 weeks thereafter • Administer ADAKVEO diluted solution by intravenous infusion over a period of 30 minutes through an intravenous line, which must contain a sterile, nonpyrogenic 0.2 micron inline filter • Do not mix or coadminister with other drugs through the same intravenous line **Please refer to full Prescribing Information for additional dosage and administration instructions.**
Important Safety Information	**INDICATION** ADAKVEO® (crizanlizumab-tmca) is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients, aged 16 years and older, with sickle cell disease.[1] **Important Safety Information[1]** **Infusion-Related Reactions** In the SUSTAIN clinical trial, infusion-related reactions (defined as occurring within 24 hours of infusion) were observed in 2 (3%) patients treated with ADAKVEO 5 mg/kg. Monitor patients for signs and symptoms of infusion-related reactions, which may include fever, chills, nausea, vomiting, fatigue, dizziness, pruritus, urticaria, sweating, or shortness of breath or wheezing. Discontinue ADAKVEO infusion for severe reactions and institute appropriate medical care. **Laboratory Test Interference: Platelet Counts** Interference with automated platelet counts (platelet clumping) has been observed following administration of ADAKVEO, in particular, when blood samples were collected in tubes containing EDTA. Run blood samples within 4 hours of blood collection or collect blood samples in tubes containing citrate. When needed, estimate platelet count via peripheral blood smear. **Pregnancy** Based on animal data ADAKVEO has the potential to cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. ADAKVEO should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the fetus.

Please see pages 2–3 for Important Safety Information. Please click here for full Prescribing Information.

Important Safety Information Continued	**Most Common Adverse Reactions** The most frequently reported adverse reactions (≥10%) in patients treated with ADAKVEO were nausea (18%), arthralgia (18%), back pain (15%), and pyrexia (11%). **Other Clinically Important Adverse Reactions** Clinically relevant adverse reactions (all grades) that were reported in <10% of patients treated with ADAKVEO included: oropharyngeal pain, abdominal pain (abdominal pain, upper abdominal pain, lower abdominal pain, abdominal discomfort, and abdominal tenderness), diarrhea, vomiting, pruritus (pruritus and vulvovaginal pruritus), musculoskeletal chest pain, myalgia, infusion-site reaction (infusion-site extravasation, infusion-site pain, and infusion-site swelling), and infusion-related reaction. **Please see full Prescribing Information here.**
Special shipping requirements	ADAKVEO® (crizanlizumab-tmca) is labeled with specific transportation and storage requirements. Care should be taken to ensure that temperature control at 2°C to 8°C (36°F–46°F) is maintained during these activities. Novartis will ship ADAKVEO in a manner that maintains its temperature to meet the requirements stated above during transport from Novartis to the product destination. Customers should call **1-888-669-6682** if they have any questions pertaining to proper shipping.
Product returns	Credit for returns is subject to Novartis' current Return Goods Policy. Please contact **1-800-526-0175** for more information.
Order information	Trade Operations Phone: **1-800-526-0175**
Product information	Novartis Medical Information Phone: **1-877-ADAKVE-0 (1-877-232-5830)** Online: medinfo.novartispharmaceuticals.com/EMedSubmitInquiry
Reimbursement information	ADAKVEO Support at PANO Phone: **1-800-282-7630** Monday through Friday 9:00 AM to 8:00 PM ET
Patient support program	**ADAKVEO Support at PANO,** part of Patient Assistance Now Oncology (PANO), is a support center consisting of insurance specialists and case managers who help patients access their medication and provide information regarding patient support programs. Dedicated support specialists help direct callers to the programs that best fit your patients' needs.

Please see pages 2–3 for Important Safety Information. Please click here for full Prescribing Information.

Reference: 1. Adakveo [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2019.

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ADAKVEO® crizanlizumab-tmca FOR IV INFUSION • 10 mg/mL

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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