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63/3

OPDIVO® (nivolumab)

7 approved indications[1]

THE ONLY* IMMUNO-ONCOLOGICAL TREATMENT WITH APPROVED 7 DIFFERENT INDICATIONS IN TURKEY.[1-4]

- RENAL CELL CARCINOMA
- NON-SMALL CELL LUNG CANCER†
- MALIGN MELANOMA
- ADJUVANT MELANOMA
- SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK†
- CLASSICAL HODGKIN LYMPHOMA††
- MSI-H/dMMR METASTATIC COLORECTAL CANCER

▼ This medicinal product is subject to additional monitoring. This triangle will allow quick identification of new safety information. Healthcare professionals are expected to report any suspected adverse reactions to TÜFAM. See section 4.8 for how to report adverse reactions.

*The claim is based on the evaluation of information in summaries of product characteristics (SmPCs) of immuno-oncology agents licensed in Turkey (Opdivo® SmPC; Yervoy® SmPC; Pembrolizumab SmPC and Atezolizumab SmPC; last accessed 05/03/2021).

†Metastatic. ††Relapsed/Refractory. **MSI-H:** Microsatellite instability-high. **dMMR:** Deficient MisMatch repair.

The indications highlighted in orange (Malignant Melanoma, RCC, cHL) have been added to the List of Reimbursable Medicines, based on Directive of 2018/1st Period of Medical and Economic Evaluation Commission.

Referanslar: 1. Opdivo® kısa ürün bilgisi. **2.** Yervoy® kısa ürün bilgisi. **3.** Pembrolizumab kısa ürün bilgisi. **4.** Atezolizumab kısa ürün bilgisi.

OPDIVO® 40 mg/4 mL ve 100 mg/10 mL IV İnfüzyonluk Çözelti Konsantresi İçeren Flakon.

BİLEŞİMİ: Her 1 mL konsantre 10 mg nivolumab içerir. 4 mL konsantre içeren 1 flakon 40 mg ve 10 mL konsantre içeren 1 flakon 100 mg nivolumab ve yardımcı madde olarak sodyum sitrat dihidrat, sodyum klorür, mannitol (E421), pentetik asit (dietilenetriaminpentaasetik asit), polisorbat 80, sodyum hidroksit (pH ayarlaması için), hidroklorik asit (pH ayarlaması için) ve enjeksiyonluk su içerir. **FARMAKOLOJİK ÖZELLİKLER:** Farmakoterapötik grup: Antineoplastik ajanlar, monoklonal antikorlar. ATC kodu: L01XC17. Nivolumab, programlanmış ölüm-1 (PD-1) reseptörüne bağlanan ve PD-L1 ve PD-L2 ile etkileşimi bloke eden insan immünoglobulin G4 (IgG4) monoklonal antikorudur (HuMAb). **ENDİKASYONLAR: Adjuvan Melanom:** Monoterapi olarak tam rezeksiyon uygulanmış ve lenf düğümü tutulumu olan yetişkinlerde adjuvan tedavi için endikedir. OPDIVO® ile tedavi edilmiş hastalar, hastalık progresyonu halinde PD-1, PDL-1 ve CTLA-4 inhibitörü kullanamazlar. Tedavi süresi 12 ay ile sınırlıdır. **Melanom:** Rezeke edilemeyen lokal ileri evre veya metastatik malign melanomu olan ECOG PS 0-1 olan, daha önce PD-1 ve PD-L1 inhibitör tedavisi kullanmamış, birinci basamak kemoterapiyi takiben hastalık progresyonu göstermiş hastaların tedavisinde progresyona kadar kullanımı endikedir. **Renal Hücreli Karsinom (RHK):** Berrak hücreli kanser içeren renal kanserli ileri evre yetişkin hastalarda endikedir. Hastaların Karnofsky performans statüsü en az 70 olmalıdır. Daha önce bir veya iki basamak antianjiojenik tedavi ve en fazla 3 basamak sistemik tedavi uygulanmış olması ve hastalık progresyonu görülmüş olmalıdır. **Klasik Hodgkin Lenfoma (cHL):** Nüks veya refrakter klasik Hodgkin Lenfoma görülen yetişkin hastalarda otolog kök hücre naklinin ve brentuksimab vedotin tedavisinden sonra monoterapi olarak endikedir. **Küçük Hücreli Dışı Akciğer Kanseri (KHDAK):** Performans durumu ECOG 0-1 olan, ve bilinen EGFR, ALK, ROS mutasyonu ve/veya semptomatik beyin metastazı olmayan, lokal ileri/metastatik küçük hücreli dışı akciğer kanseri (KHDAK) olup, daha önce bir basamak kemoterapi kullanımından sonra progresyon gelişen hastaların tedavisinde, tekrar progresyona kadar kullanımı endikedir. (Bu hastaların tedavisinde tedavi öncesi veya sonrasında başka bir PD 1/PDL 1 inhibitörü kullanılamaz.) **Skuamöz Hücreli Baş ve Boyun Kanseri (SHBBK):** Opere edilemeyen lokal ileri evre kemoradyoterapi sonrası nüks gelişen veya metastatik baş boyun (oral kavite, farenks, larenks) yassı epitel hücreli kanserlerde birinci basamak platin temelli kemoterapi sonrası ilk 6 ay içerisinde nüks gelişen hastaların tedavisinde progresyona kadar kullanımı uygundur. **Mikrosatellit İnstabilitesi Yüksek (MSI-H) veya Uyumsuzluk Onarım Eksikliği (dMMR) olan Metastatik Kolorektal Kanser (mKRK):** Nivolumab, monoterapi olarak, bir fluoropirimidin, oksaliplatin ve irinotekan ile tedaviyi takiben progresyon gösteren mikrosatellit instabilitesi yüksek (MSI-H) ya da uyumsuzluk onarım eksikliği (dMMR) olan metastatik kolorektal kanseri (mKRK) olan yetişkin hastaların tedavisinde endikedir. **POZOLOJİ VE UYGULAMA ŞEKLİ:** OPDIVO®'nun önerilen dozu 2 haftada bir 60 dakikalık intravenöz infüzyonla verilen 3 mg/kg'dır. Tedavi, klinik yarar gözlendiği sürece veya tedavi hasta tarafından artık tolere edilemeyinceye kadar sürdürülmelidir. MSI-H/dMMR mKRK için, monoterapi olarak önerilen OPDIVO® dozu, hastalık progresyonu veya kabul edilemez toksisiteye kadar 30 dakika süreyle intravenöz infüzyon olarak 2 haftada bir uygulanan 240 mg'dır. OPDIVO® sadece intravenöz yolla kullanıma yöneliktir. İnfüzyon, steril, pirojenik olmayan, 0,2-1,2 µm por boyutuna ve düşük protein bağlama oranına sahip bir in-line filtre ile uygulanmalıdır. İntravenöz "push" veya bolus enjeksiyon olarak uygulanmamalıdır. Gerekli toplam doz, doğrudan 10 mg/mL çözelti olarak infüzyonla verilebilir veya enjeksiyonluk 9 mg/mL sodyum klorür çözeltisi (%0,9) veya enjeksiyonluk 50 mg/mL glukoz çözeltisi (%5) ile 1 mg/mL'ye kadar seyreltilebilir. Geriatrik popülasyon: Yaşlı hastalarda (≥ 65 yaş) doz ayarlaması gerekli değildir. Küçük Hücreli Dışı Akciğer Kanseri ve Skuamöz Hücreli Baş ve Boyun Kanseri 75 yaş ve üzeri yaşlı hastalardaki veriler bu popülasyonla ilgili bir karar verebilmek için yeterli değildir. OPDIVO® 18 yaşın altındaki hastalarda kullanılmamalıdır. **KONTRENDİKASYONLAR:** Etkin madde veya yardımcı maddelerden herhangi birine karşı aşırı duyarlılığı olanlarda kontrendikedir. **İSTENMEYEN ETKİLER:** Nivolumab, en sık immün bağlantılı advers reaksiyonlarla ilişkilendirilmiştir. İmmün bağlantılı advers reaksiyonlar çoğu vakada uygun tıbbi tedaviyle çözülmüştür.Çeşitli tümör tiplerinde nivolumab 3 mg/kg monoterapisi ile yapılan çalışmaların (n=2578) birleştirilmiş veri setinde, en yaygın yan etki (≥ %10) yorgunluk (%30), döküntü (%17), pruritus (%13), diyare (%13) ve bulantıdır (%12). Advers reaksiyonların çoğu hafif ila orta şiddetliydi (Derece 1 veya 2). KHDAK'de minimum 24 aylık bir izlemle herhangi yeni bir güvenlilik sinyali tespit edilmemiştir. Nivolumab kullanımı ile Klasik Hodgkin Lenfomada allojenik HSCT allojenik HSCT öncesi ve sonrası hızlı başlangıçlı GVHD bildirilmiştir. **KULLANIM UYARILARI VE ÖNLEMLERİ:** Nivolumab tedavisi sırasında veya tedaviden sonraki herhangi bir zamanda bir advers reaksiyon meydana gelebileceğinden, hastalar sürekli olarak izlenmelidir (son dozu takiben en az 5 ay). Şüpheli immün bağlantılı advers reaksiyonlar için, etiyolojiyi doğrulamak veya diğer nedenleri dışlamak için uygun değerlendirmeler yapılmalıdır. Advers reaksiyonun şiddetine dayanarak, nivolumab tedavisi kesilmeli ve kortikosteroidler uygulanmalıdır. Bir advers reaksiyon nedeniyle uygulanan kortikosteroid, iyileşme sonrasında en az 1 aylık sürede azaltılarak kesilmelidir. Dozun kısa sürede kesilmesi advers reaksiyonun kötüleşmesine veya tekrarlamasına yol açabilir. Kortikosteroid kullanımına rağmen kötüleşme görülen veya iyileşme görülmeyen hastalarda kortikosteroid dışında bir immünosupresif tedavi eklenmelidir. Hasta, immünosupresif kortikosteroid dozlarını ya da diğer immünosüpresif tedavileri alırken OPDIVO® tedavisi yeniden başlatılmamalıdır. İmmünosüpresif tedavi alan hastalarda fırsatçı enfeksiyonların önlenmesi için profilaktif antibiyotikler kullanılmalıdır. Herhangi bir şiddette immün bağlantılı advers reaksiyonun tekrarlaması veya yaşamı tehdit eden herhangi bir immün bağlantılı reaksiyon görülmesi durumunda, OPDIVO® tedavisi kalıcı olarak kesilmelidir. **Böbrek yetmezliği:** Popülasyon farmakokinetik (PK) sonuçlarına dayanarak, hafif ila orta şiddette böbrek yetmezliği olan hastalarda dozun ayarlanması gerekli değildir. Şiddetli böbrek yetmezliği olan hastalardan elde edilen veriler, bu popülasyonla ilgili bir sonuç çıkaramayacak kadar sınırlıdır. **Karaciğer yetmezliği:** PK sonuçlarına dayanarak, hafif karaciğer yetmezliği olan hastalarda dozun ayarlanması gerekli değildir. Orta ila şiddetli karaciğer yetmezliği olan bilirubin > 1,5 × ila 3 × üst normal sınır [ULN] ve herhangi bir AST) veya şiddetli (toplam bilirubin > 3 × ULN ve herhangi bir AST) olan hastalarda dikkatli şekilde uygulanmalıdır. **Gebelik ve laktasyon:** Gebelik kategorisi D. Emzirmenin bebeğe ve tedavinin anneye yararı dikkate alınarak, emzirmenin veya Nivolumab tedavisinin kesilmesi konusunda bir karar verilmelidir. Üreme yeteneği/fertilite: Nivolumabın fertilite üzerindeki etkilerini değerlendiren çalışmalar yapılmamıştır. Nivolumabın erkek ve dişi fertilitesi üzerindeki etkisi bilinmemektedir. Araç ve Makine Kullanımı: Farmakodinamik özelliklerine dayanarak, Nivolumabın araç ve makine kullanma becerisini etkilemesi beklenmez. Yorgunluk gibi potansiyel advers reaksiyonlara yol açabilmesi nedeniyle, hastalara OPDIVO®'nun kendilerini ters bir şekilde etkilemediğinden emin olana dek araç veya makine kullanmaları konusunda dikkatli olmaları önerilmelidir. **Diğer tıbbi ürünler ile etkileşimler ve diğer etkileşim şekilleri:** Nivolumab insana özgü bir monoklonal antikor olduğundan, farmakokinetik etkileşim çalışmaları gerçekleştirilmemiştir. Monoklonal antikorlar sitokrom P450 (CYP) enzimleri veya diğer ilaç metabolize eden enzimler tarafından metabolize edilmediğinden, eşzamanlı uygulanan ilaçlarla bu enzimlerin inhibisyonu veya indüksiyonunun Nivolumabın farmakokinetiğini etkilemesi beklenmez. Sistemik immünosüpresyon:Farmakodinamik aktiviteyle etkileşim potansiyeli nedeniyle Nivolumaba başlamadan önce, başlangıçta sistemik kortikosteroidlerin ve diğer immünosupresanların kullanımından kaçınılmalıdır. Yine de, immün bağlantılı advers reaksiyonların tedavi edilmesi için Nivolumaba başlandıktan sonra sistemik kortikosteroidler veya diğer immünosüpresanlar kullanılabilir. Başlangıç sonuçları, OPDIVO® tedavisine başlandıktan sonra sistemik immünosüpresyon kullanımının, Nivolumaba verilen yanıtı bozmadığını göstermektedir. Geçimlilik çalışmaları yapılmadığından, bu tıbbi ürün diğer tıbbi ürünlerle karıştırılmamalıdır. OPDIVO®, diğer ajanlarla aynı intravenöz hatta aynı zamanda infüze edilmemelidir. DOZ AŞIMI: Hastanın advers reaksiyon bulgu ve semptomları açısından yakından gözlemlenmesi ve uygun semptomatik tedaviye başlanması önerilir. **SAKLAMA KOŞULLARI:** 2 °C - 8 °C arasında buzdolabında saklayınız. Dondurmayınız. Işıktan korumak için orjinal ambalajında saklayınız. **RAF ÖMRÜ:** Açılmamış flakon: 36 ay. Açılmış flakon: mikrobiyolojik nedenlerle, açılan tıbbi ürün derhal infüze edilmeli ya da seyreltilerek infüze edilmelidir, hemen kullanılmaması halinde OPDIVO®'nun ışıktan korunduğunda 2 °C - 8 °C'de kimyasal ve fiziksel kullanım içi stabilitesinin 24 saat, oda ışığı altında 20 °C - 25°C'de ise en fazla 8 saat olduğu gösterilmiştir (toplam 24 saatlik sürenin bu 8 saatlik periyoduna ürünün uygulandığı periyod dahildir). **TİCARİ TAKDİM ŞEKLİ VE AMBALAJ İÇERİĞİ:** OPDIVO® 40 mg/4 mL ve 100 mg/10 mL IV İnfüzyonluk Çözelti Konsantresi İçeren Flakon, Steril. Reçete ile satılır. **Fiyatı:** OPDIVO® 100 MG/10 ML IV İNFÜZYONLUK ÇÖZELTİ KONSANTRESİ İÇEREN 1 FLAKON KDV Dahil Perakende Satış Fiyatı: 7.788,13 TL OPDIVO® 40 MG/4 ML IV İNFÜZYONLUK ÇÖZELTİ KONSANTRESİ İÇEREN 1 FLAKON KDV Dahil Perakende Satış Fiyatı: 3.132,50 TL **Fiyat Onay Tarihi:** 20.02.2021. **Ruhsat Sahibi:** Bristol-Myers Squibb İlaçları İnc.İstanbul Şubesi; Sun Plaza No:5 Sarıyer– İstanbul. Ruhsat Tarihi ve No: 40 mg/4 mL IV: 19.04.2017 – 2017/257; 100 mg/10 mL IV: 19.04.2017 - 2017/256. **Güncel KÜB'ün Onay Tarihi:** 20.03.2019.

For more information and summary of product characteristics (SmPC), please visit www.bms.com/tr or contact Bristol Myers Squibb Medical Information Department by calling 0216 282 16 25 and/or sending an e-mail to medinfo.turkey@bms.com.

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Gülhane Medical Journal (Gulhane Med J) is the official, scientific, peer-reviewed, international journal of Gülhane Faculty of Medicine, University of Health Sciences Turkey. The journal accepts submissions on all aspects of general medicine. Featured article types include original articles, case reports, reviews, and letters to the editor. The history of the Gülhane Medical Journal dates back to 1871 and it was named with its current title in 1999.

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4. **Letter to the editor (and their responses)**

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Original articles should be designated either basic research or clinical research.

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Original article	250	2000 to 5000	Unlimited	40	5
Review article	250	2000 to 4000	3	50	3
Case report	100	500 to 1000	5	15	2
Letter to the editor	-	250 to 500	3	5	-

*Excludes abstract, acknowledgments, conflict of interest statement, references, and tables; minimum and maximum word counts.

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The Methods section should include a statement indicating that the research was approved by an independent local, regional or national review body (e.g., ethics committee, institutional review board). If the study includes human subjects, the author should declare openly that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans (link- https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/), and Uniform Requirements for manuscripts submitted to Biomedical journals (link- http://www.icmje.org/). The name of the institution and the code of approval (i.e., approval number) must be provided. Authors should include a statement in the manuscript about informed consent obtained from their participants. According to the most recent regulations by the Turkish Academic Network and Information Center (ULAKBIM), the authors (s) of a case report must include a statement in their manuscript that written, informed consent was obtained from the patient.

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The text should be in simple, single-column format. Using MS word processor, Times New Roman font and 11- or 12-point font size should be chosen. The text and references should be double-spaced.

Importantly, the title page must be uploaded separately, no page breaks should be used and all pages should be numbered (below, centered) consecutively.

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All submissions should include a cover letter and complete contact information for the corresponding author. The authors must declare in this letter that their submitted article has neither been published in any journal, nor been simultaneously submitted to another journal. Whether the authors have published or submitted any related papers from the same study should be stated. Authors may also use this letter for confidential contact with the editor.

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It should be structured according to Aims, Methods, Results, Conclusions

Keywords

Up to six keywords should be included in the manuscript.

Main document

It should be divided into the following sections: Introduction; Methods; Results; Discussion.

A case report should be structured as follows; introduction, Presentation of Case, Discussion, Conclusion.

Acknowledgments (mandatory)

This section must include list of author contributions, credits, and other information. Author contributions must be listed in accordance with ICMJE authorship criteria. Funding must be described in detail including valid codes. Authors are responsible for the completeness of the information that should exist in the acknowledgement.

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World Health Organization. WHO Criteria for Diagnosis of Osteoporosis. http://www.4bonehealth.org/education/world-health-organization-criteria-diagnosis-osteoporosis/. Accessed June 15, 2017.

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