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Sürdürülebilir tam iyileşme için
Orta ile şiddetli plak tip psoriasis tedavisiyle¹⁻³

HAYATA ÖZGÜRLÜK

Hastaların yaşamlarını kolaylaştırma
yolunda geliştirdiğimiz çözümlerle,
uzun yıllara dayanan deneyim ve
güvenimizle, yaşamlarda iz bırakmaya
devam ediyoruz.

Referanslar:

1. Papp K.A. et al Br J Dermatol. 2021 Jun 22
2. Gordon KB, et al. Lancet. 2018;392 (10148): 650–661.
3. Skyrizi Kısa Ürün Bilgisi

Bu ilaç ek izlemeye tabidir. Bu üçgen yeni güvenlik bilgisinin hızlı olarak belirlenmesini sağlayacaktır. Sağlık mesleği mensuplarının şüpheli advers reaksiyonları TÜFAM'a bildirmeleri beklenmektedir. Bakınız Bölüm 4.8 Advers reaksiyonlar nasıl raporlanır?

SKYRIZI 75 mg/0.83 mL enjeksiyonluk çözelti içeren kullanıma hazır enjektör

FORMÜLÜ: Her tek kullanımlık enjektör 0.83 mL çözelti içerisinde 75 mg risankizumab içerir. **ENDİKASYONLAR:** Psoriasis; sistemik tedavilere aday olan ve konvansiyonel sistemik tedavilere (örneğin siklosporin, metotreksat veya fototerapi) yanıt vermeyen, bunları kontrendiklediği veya bu tedavileri tolere edemeyen erişkin hastalarda orta ile şiddetli plak tip psoriasis tedavisinde etkilidir. **KULLANIM SEKİ VE DOZU:** SKYRIZI, psoriasis teşhisi ve tedavisinde uzman bir doktorun gözetimi ve rehberliği altında kullanıma yöneliktir. Önerilen doz, 0. haftada, 4. haftada ve ardından 12 haftada bir subkütan enjeksiyonla uygulanır (50 mg dir (iki 75 mg enjeksiyon)). 16 haftalık tedavinin ardından, tedaviye yanıt vermeyen hastalarda tedavinin kesilmesine yönelik değerlendirme yapılmalıdır. Başlangıçta kesimi yanıt veren bazı hastalarda 16 haftayı aşan devamlı tedavinin ardından düzenli görülmüştür. Bir dozun unutulması durumunda, doz en kısa sürede uygulanmalıdır. Ardından, doz uygulamaya planlanan şekilde devam edilmelidir. **KONTRENDİKASYONLAR:** Etkin maddeye veya yardımcı maddelerden herhangi birine aşırı duyarlılık durumunda ve klinik olarak anlamlı aktif enfeksiyonlarda kontrendikedir. **UYARILAR VE ÖNEMLER:** Risankizumab enfeksiyon riskini artırabilir. Kronik enfeksiyonu veya nökseden enfeksiyon hikayesi olan veya enfeksiyon için bilinen risk faktörleri olan hastalarda risankizumab dikkatli kullanılmalıdır. Klinik olarak anlamlı aktif enfeksiyonu olan hastalarda, enfeksiyon iyileşene veya uygun şekilde tedavi edilmeye kadar risankizumab tedavisi başlatılmamalıdır. Risankizumab ile tedavi edilen hastalar, klinik olarak anlamlı kronik veya akut enfeksiyon belirtileri veya semptomları ortaya çıkarsa tıbbi yardım almadan konusunda bilgilendirilmelidir. Hastada bu tür bir enfeksiyon ortaya çıkması veya hastanın standart enfeksiyon tedavisine yanıt vermemesi durumunda, hasta yakından izlenmelidir ve enfeksiyon geçene kadar risankizumab uygulanmamalıdır. Risankizumab tedavisine başlamadan önce, hastalar tüberküloz (TB) enfeksiyonu için değerlendirilmelidir. Risankizumab alan hastalar, aktif TB belirtileri ve semptomları için izlenmelidir. Yeterli tedavi seyrinin doğrulanmadığı geçmişte latent ya da aktif TB öyküsü olan hastalarda, risankizumaba başlamadan önce anti-TB tedavisi düşünülmelidir. Ciddi bir aşırı duyarlılık reaksiyonu olursa, risankizumab uygulaması hemen durdurulmalı ve uygun tedavi başlatılmalıdır. Biyolojiler veya fototerapi dahil olmak üzere immunosüpresantlarla kombine risankizumabın etkinliği ve güvenliği araştırılmamıştır. 65 yaş ve üstü hastalar ile ilgili sınırlı güvenlik bilgisi bulunmaktadır. 6-18 yaş arası hastalarda SKYRIZI'nin güvenliği ve etkinliği henüz belirlenmemiştir. SKYRIZI'nin 6 yaşından küçük çocuklarda orta veya şiddetli plak psoriasis endikasyonu için uygun bir kullanımı bulunmamaktadır. **İLAC ETKİLEŞİMLERİ VE DİĞER ETKİLEŞİMLER:** Risankizumab tedavisinin ardından kafein (CYP1A2 substratı), varfarin (CYP2C9 substratı), omeprazol (CYP2C19 substratı), metoprolol (CYP2D6 substratı) ve midazolam (CYP3A substratı) maruziyeti, risankizumab tedavisi öncesindeki maruziyetleriyle karşılaştırılabilir ölçüde idi, bu da bu enzimlerle klinik olarak anlamlı ilaç etkileşimi olmadığının belirtmektedir. Popülasyon farmakokinetik analizleri risankizumab maruziyetinin, klinik çalışmalar sırasında plak psoriasis olan hastalar tarafından kullanılan eşzamanlı ilaçlar (metformin, atorvastatin, lisinopril, amlopidin, ibuprofen, asetilsalisilat ve levotiroksin) tarafından etkilenmediğini göstermektedir. **GEBELİK VE LAKTASYON:** Gebelik kategorisi B'dir. Çocuk doğurma potansiyeli olan kadınlar, tedavi süresince ve tedaviden sonra en az 21 hafta boyunca etkili bir doğum kontrol yöntemi kullanmalıdır. Hamile kadınlarda risankizumab kullanımına dair sınırlı sayıda veri (300'den az hamilelik sonucu) mevcuttur ya da veri bulunmamaktadır. Risankizumabın anne sütüne geçip geçmediği bilinmemektedir. İnsan IgG'nin doğumdan sonraki ilk günlerde anne sütüne geçtiği bilinmekte olup, hemen ardından düşük konsantrasyonlara düşer. Bu sebeple bu kısa dönem sırasında anne sütüyle beslenen bebeklere yönelik risk göz ardı edilemez. Emzirmenin çocuğa yararı ve risankizumab tedavisinin kadına yararı göz önünde bulundurularak risankizumab tedavisinin kesilip kesilmeyeceğine/tedavisinden uzak durulup durulmayacağına karar verilmelidir. **ARAC VE MAKİNE KULLANIMI ÜZERİNDEKİ ETKİLER:** SKYRIZI arac ve makine kullanımı üzerinde herhangi bir etkiye sahip değildir ya da etkisi ihmal edilebilir düzeydedir. **İSTENMEYEN ETKİLER:** Çok yaygın (>1/10) görülen istenmeyen etkiler: Enfeksiyon ve enfeksiyonlar. Üst solunum yolu enfeksiyonları, solunum yolu enfeksiyonu (örneğin bakteriyel veya viral), sinüzit (akut, dahili), rinit, nazofarenjit, faranjit (viral dahil), tonsitit. Yaygın (>1/100 ila <1/10) görülen istenmeyen etkiler: Enfeksiyon ve enfeksiyonlar. Tinea enfeksiyonları (ayak mantarı, ayak mantarı, vücudtaki tinea), tinea versikolor, tinea manuum, onikomikoz. Sinir sistemi hastaları: Baş ağrısı (baş ağrısı, tansiyon baş ağrısı, sinüs baş ağrısı), deri ve deri altı doku hastalıkları: Kasıntı. Genel hastalıklar ve uygulama bölgesine ilişkin hastalıklar: Yorgunluk (asteni), enjeksiyon yeri reaksiyonları (enjeksiyon yerinde morarma, eritem, hematoma, hemoraj, tahirs, ağrı, kaşıntı, reaksiyon, şişme). **DOZ ASİMİ:** Doz aşımı durumunda hastanın advers reaksiyonlara ilişkin belirti ve semptomlara karşı izlenmesi ve uygun semptomatik tedavinin derhal uygulanması tavsiye edilmektedir. **RAF ÖMRÜ:** 24 aydır. **SAKLAMA KOSULU:** 2°C-8°C arasında buzdolabında saklanmalıdır. Ürün, ışıktan korunmak için, enjektör kullanımı ana kadar orijinal ambalaj kutusunda saklanmalıdır. Dondurulmamalıdır. **AMBALAJIN NİTELİĞİ VE İÇERİĞİ:** SKYRIZI otomatik iğne muhafazasına yerleştirilmiş, sabit iğne ve iğne kapacağına sahip kullanıma hazır cam enjektör içerisinde bulunmaktadır. Her tek kullanımlık enjektör 0.83 mL içerisinde 75 mg risankizumab içerir. **RUHSAT SAHİBİ:** AbbVie Tıbbi İlaçlar Sanayi ve Ticaret Limited Şirketi, Saray Mah. Dr. Adnan Büyükdüz Cad. 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Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the international committee of medical journal editors [published online June 6, 2017]. *Ann Intern Med.* doi: 10.7326/M17-1028.

World Health Organization. WHO Criteria for Diagnosis of Osteoporosis. Last Accessed Date: 15.06.2017. Available from: <http://www.4bonehealth.org/education/world-health-organization-criteria-diagnosis-osteoporosis/>

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