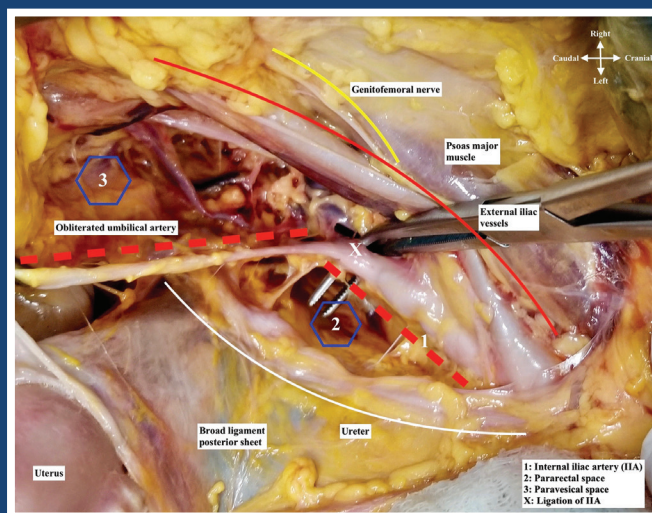




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FARKLI GEREKSİNİMLER**

Oral tedaviyi tercih eden anormal uterin kanamalı kadınlarda¹

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Rahim içi sistem tercih eden anormal uterin kanamalı kadınlarda²

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Tinidazol
Tiokonazol
Lidokain

Candida albicans'ın oluşturduğu

► **Kandidal vulvovajinit,**

Gardnerella vaginalis ve anaerob bakterilerin oluşturduğu

► **Bakteriyel vajinozis,**

Trichomonas vaginalis'in oluşturduğu

► **Trikomonal vajinit,**

► **Mikst vajinal enfeksiyonların**

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Tedavide rahatlık için*

* Trivag Kısa Ürün Bilgisi

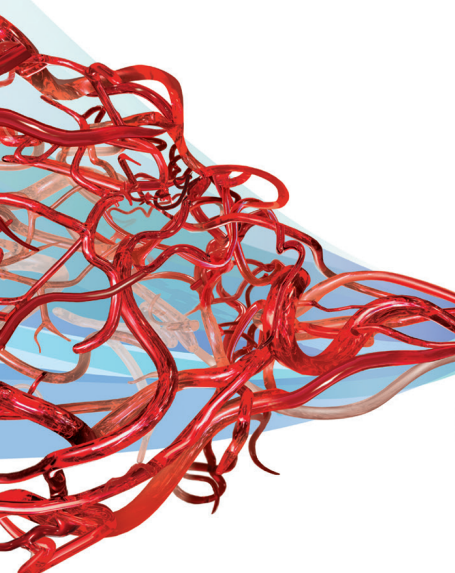
ÜRÜN ADI: TRIVAG 300 mg/200 mg/100 mg ovül FORMÜLÜ: Her bir ovül 300 mg tinidazol, 200 mg tiokonazol, 100 mg lidokain içerir. TERAPÖTİK ENDİKASYONLAR: Candida albicans'ın oluşturduğu kandidal vulvovajinit; Gardnerella vaginalis ve anaerob bakterilerin oluşturduğu bakteriyel vajinoz ve Trichomonas vaginalis'in oluşturduğu trikomonal vajinit ile mikst vajinal enfeksiyonların tedavisinde kullanılır. KULLANIM ŞEKLİ VE DOZU: Gece yatmadan önce bir ovül, 3 gün süreyle uygulanır. TRIVAG sırtüstü yatar pozisyonda, paketin içindeki parmaklıkların yardımı ile vajen derinliğine uygulanmalıdır. İSTENMEYEN ETKİLER: Güçsüzlük, bitkinlik, halsizlik, baş ağrısı, baş dönmesi, ağızda metalik/acı tat, mide bulantısı, anoreksi, iştahsızlık, midede gaz toplanması, dispepsi, abdominal kramp, epigastrik rahatsızlık, kusma, konstipasyon, idrar renginde koyulaşma. GEBELİK VE LAKTASYON: Gebelik kategorisi C'dir. Tinidazol anne sütüne geçtiğinden emzirme döneminde tedavi sırasında bebek süten kesilmelidir, tedavi bittikten 72 saat sonra emzirmeye devam edilmelidir. DİĞER TIBBİ ÜRÜNLERLE ETKİLEŞİMLER VE DİĞER ETKİLEŞİM ŞEKİLLERİ: Birlikte kullanıldığında tinidazolün emilmesine bağlı olarak etkileşim görülebilir; asenokumarol, anisindon, dikumarol, fenindion, fenpropion, varfarin, kolestramin, simetidin, siklosporin, disalfram, fluourasili, fosfenito, ketokonazol, lityum, fenobarbital, fenitoin, rifampin, takrolimus, CYP3A4 indükleyicileri/inhibitörleri, Tiokonazolün emilmesine bağlı olarak etkileşim görülebilir; oksikodon, Lidokainin emilmesine bağlı olarak etkileşim görülebilir; propranolol, simetidin, antiaritmik ürünler, fenitoin veya barbitüratlar. KONTRENDİKASYONLARI: Bileşimindeki etkin maddelere veya bunların türevlerine karşı aşırı duyarlılığı bulunanlarda, gebeliğin ilk üç ayında, emzirme döneminde, organik nörolojik bozukluğu bulunanlarda, kan diskrazisi tablosu veya geçmişi bulunan hastalarda. ÖZEL KULLANIM UYARILARI VE ÖNLEMLERİ: Vajinal yoldan kullanılmamalıdır. Geçici lökopeni ve nötropeni gelişebilir. Tedavi süresince ve tedavi bittikten 3 gün sonrasına kadar alkol alınmamalıdır. Cinsel olgunluğa erimemiş kız çocuklarında ve bakirelerde kullanılmamalıdır. Kardiyovasküler hastalıkları olanlarda dikkatli kullanılmamalıdır. Kontraseptif diyafram ve prezervatifle temas etmemelidir. Lidokain özellikle yüksek dozda ve geniş deri yüzeylerine, bilhassa da oklüzyon altında uygulandığında kalp ritm bozuklukları, nefes alma zorluğu, koma ve hatta ölüme yol açabilmektedir. Spermisidler, vajinal duşlar veya vajinal yoldan uygulanan diğer ürünlerle birlikte kullanılmamalıdır. Trikomonal vajinit vakalarında eş tedavisi de gereklidir. TİCARİ TAKDİM ŞEKLİ VE FİYATI: Trivag ovül (Ruhsat tarihi ve no: 29.09.2017-2017/742) 16,53 TL. (Fiyat Tarihi: Mayıs 2018) Ruhsat Sahibi: Bilim İlaç San. ve Tic. A.Ş. Son Güncelleme: Mayıs 2018. Reçeteli satılır. Daha geniş bilgi için "BİLİM İLAÇ SAN. ve TİC A.Ş. 34440 Beyoğlu-İSTANBUL" adresine başvurunuz. Ürünlerimiz ile ilgili advers olayları PHARMACOVIGILANCE@bilimilac.com adresine e-posta göndererek veya 0 212 365 1717 iletişim numarasını arayarak ürün güvenliliği sorulusuna bildirilebilirsiniz.

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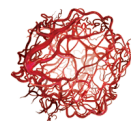
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Referanslar: 1. Pinedo ve ark. *The Oncologist* 2000; 5(suppl.1):1-2. 2. Hurwitz ve ark. *N. Engl. J. Med.* 2004; 350:2335-42. 3. Tewari SK et al. *N Engl J Med* 2014; 370:734-743.

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100 mg
100 Mikrogramm / 24h
1. April 1998

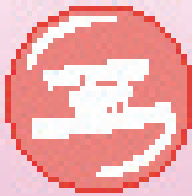


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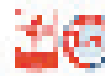
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100 mg / 24h
1. April 1998

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Referanslar: 1. Lefter E, Stevens DA. Antimicrob Agents Chemother. 1984; 25(4):450-454. 2. Sobel JD, et al. Clin Infect Dis. 2001;33(8):1341-6. 3. Sobel J, et al. Infect Dis Obstet Gynecol 2001;9:9-15. 4. Gynomax-XL KÜB. **Gynomax® XL KÜB ÖZETİ:** ÜRÜN ADI: Gynomax® XL 200 mg/ 300 mg/ 100 mg Vajinal Ovül. **FORMÜL:** 1 vajinal ovül 200 mg tiokonazol, 300 mg tinidazol, 100 mg lidokaine eşdeğer lidokain HCl içerir. **ENDİKASYONLAR:** Kandidal vulvovajinit; bakteriyel vajinoz ve trikomonal vajinit ile karma vajinal enfeksiyonların tedavisinde kullanılır. **KULLANIM ŞEKLİ VE DOZU:** Hekim tarafından başka şekilde tavsiye edilmediği takdirde, gece yatmadan önce bir ovül 3 gün süreyle uygulanır. **UYGULAMA ŞEKLİ:** Vajinal. **KONTRENDİKASYONLAR:** Bileşimindeki etkin maddelere veya bunların türevlerine karşı aşırı duyarlılığı bulunanlarda; gebeliğin ilk üç ayında; emzirme döneminde; organik nörolojik bozukluğu bulunanlarda, kan diskrazisi tablosu veya geçmişte bulunan hastalarda kullanılmamalıdır. **ÖZEL KULLANIM UYARILARI ve ÖNLEMLERİ:** Disülfram benzeri reaksiyon görülebileceğinden tedavi süresince ve tedavi bittikten 3 gün sonrasına kadar alkol alınmamalıdır. Lastikte hasar yapabileceğinden ovüller kontraseptif diyafram ve prezervatifle temas etmemelidir. Spermisidler, vajinal duşlar veya vajinal yoldan uygulanan diğer ürünlerle birlikte kullanılmamalıdır. Trikomonal vajinit vakalarında eş tedavisi de gereklidir. Çift doz kullanılmamalıdır. Menstruasyon döneminde kullanıldığında etkisi azalabileceğinden veya kullanım zorluğu meydana gelebileceğinden, bu dönemde kullanılmaması önerilmektedir. Ovüller yutulmamalı veya başka bir yoldan uygulanmamalıdır. Cinsel olgunluğa erişmemiş kız çocuklarında ve bakirelerde kullanılmamalıdır. **İLAC ETKİLEŞİMLERİ VE GEÇİMSİZLİKLER:** Azenokumarol, anisindion, dikumarol, fenindion, fenprokumon, varfarin, kolestiramin, simetidin, siklosporin, disülfram, fluorourasil, fosfenito, ketokonazol, litium, fenobarbital, fenitoin, rifampin, takrolimus ve CYP3A4 indükleyicileri/inhibitörleri ile tinidazolün emilimine bağlı etkileşim görülebilir. Oksikodon ile tiokonazolün emilimine bağlı etkileşim görülebilir. Propofol, simetidin, antiaritmik ürünler, fenitoin ve barbitüratlar ile lidokainin emilimine bağlı etkileşim görülebilir.

GEBELİK ve EMZİRME: Gebelik kategorisi: C. Tinidazol anne sütüne geçtiğinden emzirme döneminde tedavi sırasında bebek sütten kesilmelidir, tedavi bittikten 72 saat sonra emzirmeye devam edilmelidir. **ARAC ve MAKİNE KULLANIMI:** Herhangi bir etkisi bulunmamaktadır. **İSTENMEYEN ETKİLER:** Intravajinal uygulamada, tinidazol, tiokonazol ve lidokainin kan düzeyleri sistemik kullanıma kıyasla daha düşük olacağından yan etkiler çok daha seyrek görülür. Yaygın: Güçsüzlük, bitkinlik, halsizlik, baş ağrısı, baş dönmesi, ağızda metalik/acı tat, mide bulantısı, anoreksi, iştahsızlık, mideye gaz toplanması, dispepsi, abdominal kramp, epigastrik rahatsızlık, kusma, konstipasyon, idrar renginde koyulaşma. Bilinmiyor: Lökeni (geçici), nötrojeni (geçici), alerjik reaksiyonlar (ağır vakalarda anafilaktik şok görülebilir), ataksi, koma (nadir), konfüzyon (nadir), depresyon (nadir), uyuşukluk, sersemlik hali, insomnia, uyku bozuklukları, anksiyete, psikoz, nöbet, konfüzyon bozulması, ajitasyon, kaygı, vertigo, periferik nöropati, konvülsiyon, kramp, aşırı heyecan, dezoryantasyon, ofori, halüsinasyonlar, hiperestezi, hipoestezi, letarji, aritmi, bradikardi, konvülsiyon, kramp, kardiyovasküler kollaps, defibrilatör eşliğinde artma, ödem, yüz kızarması, kalp bloğu, hipotansiyon, sinüs düğümünde süpresyon, karın ağrısı, diyare, paslı dil (nadir), stomatit, dil renginde değişiklik, ağız kuruluğu, psödomembranoz kolit, kaşıntı, ürtiker, anjionörotik ödem, kutanoöz erüpsiyon, lokal yanma, üriner yanma, ödem, lokal iritasyon, kaşıntı, vajinal akıntı, dispareni, nokturi, vajinal ağrı. **DOZ AŞIMI ve TEDAVİSİ:** Doz aşımında içerdiği etkin maddelere bağlı sistemik etkiler görülebilir; tinidazolün doz aşımına bağlı yan etkileri bilinmemektedir, tiokonazolün lokal uygulamaya ile doz aşımı mümkün değildir. Lidokain topikal olarak çok yüksek dozda uygulandığında kalp ritim bozuklukları, nefes alma zorluğu, koma ve hatta ölüme yol açabilmektedir. **RAF ÖMRÜ ve SAKLAMA KOŞULLARI:** 36 ay-25°C'nin altındaki oda sıcaklığında saklayınız. **TİCARİ TAKDİM ŞEKLİ:** PVC/LDPE çift katlı folyo ovül ambalajı, 3 ovül. **FİYAT:** 41,16 TL (Şubat 2019 itibarıyla). **ÜRETİM YERİ:** Exeltis İlaç San. ve Tic. A.Ş./Cerkezköy-TEKİRDAĞ **RUHSAT SAHİBİ:** Exeltis İlaç San. ve Tic. A.Ş. Kültür Mah. Nispetiye Cad. No: 56 Akmerkez B Blok Kat:6 D:574 Etiler Beşiktaş / İSTANBUL. **RUHSAT TARİH/NO:** 04.02.2013-248/3. **KÜB Güncellenme Tarihi:** 07.09.2018 **REÇETE İLE SATILIR. GERİ ÖDENİR.** Kısaltılmış KÜB güncellenme tarihi: 26.02.2019 Daha geniş bilgi için firmamıza başvurunuz. Tel: 0 212 365 93 30, infoTR@exeltis.com. Herhangi bir şüpheli advers reaksiyon ile karşılaşılmaması halinde TUFAM'a bildiriniz. (www.titck.gov.tr; e-posta: tufam@titck.gov.tr) Tel:0 800 314 00 08; Faks: 0 312 218 35 99.

