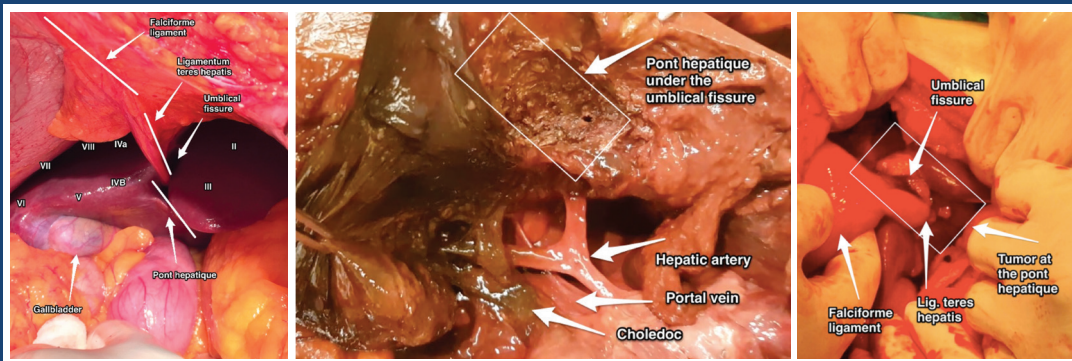




TURKISH-GERMAN GYNECOLOGICAL EDUCATION and RESEARCH FOUNDATION

# Journal of the Turkish-German Gynecological Association



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Venöz veya arteriyel trombotik/tromboembolik olayların (örneğin derin ven trombozu, pulmoner emboli, miyokard enfarktüsü) veya serebrovasküler olayın varlığı ya da öyküsü, Tromboz prodromu varlığı veya öyküsü (örneğin geçici iskemik atak, anjina pektoris), Fokal nörolojik belirtili migren öyküsü, Vasküler tutulumlu diabetes mellitus, Venöz veya arteriyel tromboz için ciddi ya da bir çok risk faktörünün varlığı da kontrendikasyon olarak kabul edilir (Bkz. Uyanlar/Önlemler), Pankreatit veya şiddetli hipertrigliseridemi ile bağlantılı pankreatit öyküsü, Karaciğer fonksiyon değerleri normale dönmedikçe, ciddi karaciğer hastalığı öyküsü veya varlığı, Şiddetli veya akut böbrek yetmezliği, Karaciğer tümörü varlığı veya öyküsü (iyi veya kötü huylu), Eğer seks steroidlerinden etkilenecekse genital organların veya memenin bilinen ya da şüpheli malign hastalıkları, Tanı konulmuş vaginal kanama, Bilinen gebelik veya şüphesi, Etkin ya da yardımcı maddelerden herhangi birine aşırı duyarlılık hali. **Uyanlar/Önlemler:** Dolaşım bozuklukları: Epidemiyolojik çalışmalar, kombine oral kontraseptif kullanımıyla miyokard enfarktüsü, inme, derin ven trombozu ve akciğer embolisi gibi arteriyel ve venöz trombotik/tromboembolik hastalıkların risk artışı arasında bir ilişki bulunduğunu göstermektedir. Bu olaylar ender olarak ortaya çıkmaktadır. Derin ven trombozu ve/veya pulmoner emboli şeklinde ortaya çıkan venöz tromboemboli (VTE) tüm kombine oral kontraseptiflerin kullanımında ortaya çıkabilir. Kombine oral kontraseptif kullanımlarında, çok ender olarak, hepatik, mezenterik, renal, serebral veya retinal venler ve arterler gibi diğer kan damarlarında da tromboz bildirilmiştir. Kombine oral kontraseptif kullanımı ile bu olayların ortaya çıkması arasındaki nedensel ilişki halen tartışmalıdır. Venöz veya arteriyel trombotik/tromboembolik durumlar ya da serebrovasküler olay riski aşağıdaki faktörlerle artar: Yaş, Sigara kullanılması, Olası aile öyküsü, Obesite, Dislipoproteini, Hipertansiyon, Migren, Kalp kapak hastalığı, Atriyal fibrilasyon, Uzun süreli immobilizasyon, Lohusalık döneminde tromboemboli gelişimi riskinin arttığı göz önüne alınmalıdır. Kombine oral kontraseptiflerin kullanılması sırasında, migrenin sıklığında ve şiddetinde artış ortaya çıkması (bir serebrovasküler olay habercisi olabilmesi açısından) ilacın derhal kesilmesi için bir neden olabilir. **Tümörler:** Bazı epidemiyolojik çalışmalar uzun süre kombine oral kontraseptif kullanımlarında servikal kanser riskinde artış görüldüğü bildirilmiştir. Ancak bu bulguların seksüel davranış ve human papilloma virus (HPV) gibi diğer faktörlerle bağlantısı da halen tartışılmaktadır. 54 epidemiyolojik çalışmayı kapsayan bir meta-analiz sonuçlarına göre halen oral kontraseptif kullanan kadınlarda meme kanserine rastlanma oranında hafif bir artış olduğu rapor edilmiştir. Bu risk artışının oral kontraseptif kullanımının kesilmesiyle birlikte 10 yıl içinde göreceli olarak ortadan kalkar. Meme kanseri görülme sıklığı 40 yaşın altındaki kadınlarda düşük olduğundan, bu açıdan meme kanseri riski fazla anlamlı değildir. Kombine oral kontraseptif kullanımlarında nadir olgularda iyi huylu, çok nadiren de habis karaciğer tümörleri gözlemlenmiştir. Sınırlı olguda bu tümörler yaşamı tehdit eden batin içi kanamalara yol açar. **Diğerleri:** Böbrek yetmezliği olan hastalarda potasyum atılım kapasitesi sınırlı olabilir. Hipertrigliseridemi olan ya da bu şekilde bir aile öyküsüne sahip bulunan kadınlarda, kombine oral kontraseptif kullanımıyla pankreatit gelişimi riskinde artış ortaya çıkabilir. Kombine oral kontraseptif alan kadınların çoğunda kan basıncında hafif artış görüldüğü bildirilmesine rağmen, klinik olarak anlamlı artış enderdir. Karaciğer fonksiyonlarında görülen akut ve kronik değişiklikler, kombine oral kontraseptif kullanımının fonksiyon testi değerleri normale dönene dek kesilmesini gerektirebilmektedir. Gebelik sırasında ilk kez ortaya çıkan ya da daha önce seks steroidlerinin kullandığı sırada görülmüş olan kolestatik sarılığın nükesi etmesi kombine oral kontraseptif kullanımının kesilmesi gerekliliğini göstermektedir. Kombine oral kontraseptif kullanan diyabetik kadınlar diyetle birlikte gözlenmelidir. Crohn hastalığı ve ülseratif kolit kombine oral kontraseptif kullanımı ile ilişkilendirilmiştir. Özellikle gebelik maskesi öyküsü olan kadınlarda daha belirgin olmak üzere kloazma ortaya çıkabilir. Kloazma eğilimi olan kadınlar kombine oral kontraseptif kullanımı esnasında güneşe çıkmaktan ya da ultraviyole ışınlarına maruz kalmaktan kaçınılmalıdır. Azalmış etkinlik: Kombine oral kontraseptiflerin etkinliği tablet alımı unutulduğunda (Bkz. Tablet alımı unutulduğunda), mide-bağırsak bozuklukları halinde (Bkz. Mide-bağırsak bozuklukları durumunda), ya da eş zamanlı ilaç tedavilerinde (Bkz. İlaç Etkileşimleri) azalabilir. Azalmış siklus kontrolü: Tüm kombine oral kontraseptiflerde, özellikle kullanımın ilk aylarında düzensiz kanamalar (lekelenme veya kırma kanamaları) gelişebilir. Eğer kanama düzensizliği devam eder veya kanamalar düzenliken ortaya çıkarsa non-hormonal etkenler göz önüne alınmalı ve malignite veya gebeliğin ekarte edilmesi için kürtajın da dahil olabileceği uygun tanısal girişimlerde bulunulmalıdır. Bazı kadınlarda tablet alınmayan dönemde çekilme kanaması oluşabilir. **Yan etkiler/advers etkiler:** Kombine oral kontraseptiflerin kullanımıyla ilişkilendirilen en ciddi yan etkiler "Uyanlar/Önlemler" bölümünde ele alınmıştır. Aşağıdaki diğer yan etkiler kombine oral kontraseptif kullanımlarında bildirilmiş ve ilişkileri ne de yanlışlığı kanıtlanmıştır. Göz: kontakt lense toleranssızlık; Gastrointestinal sistem: bulantı, kusma, batında ağrı, diyare; İmmün sistem: hipersensitivite; Metabolizma ve beslenme: sıvı retansiyonu, ağrılı artros, ağrılı azalmış; Sinir sistemi: baş ağrısı, migren, libido azalması, depresif duyu durumu, duyu durum değişiklikleri; Üreme sistemi ve meme: meme hassasiyeti, meme ağrısı, memede hipertrofi, memede akıntı, vaginal akıntı; Cilt ve ciltaltı: döküntü, ürtiker, eritema nodosum, eritema multiforme. **İlaç etkileşimleri:** Oral kontraseptifler ve diğer ilaçlar arasında etkileşimler kırma kanamalarına ve/veya kontraseptif başarısızlığıyla açılabilir. Aşağıdaki etkileşimler literatürde bildirilmiştir. Hepatik metabolizma: Mikroozomal enzimler etkileyen ilaçlar (ör. fenitoin, barbitüratlar, primidon, karbamazepin, rifampisin ve muhtemelen okskarbazepin, topiramet, felbamet, ritanovir, griseofulvin ve "St. John's wort" içeren ürünler) olan etkileşimler, seks hormonlarının klrensinsinin artması ile sonuçlanabilir. Enterohepatik dolaşım etkileşimleri: Belirli antibiyotik ajanların (ör. penisilinler, tetrasiklinler) verilmesi durumunda estrojenlerin enterohepatik dolaşımının azalabileceğini ve bunun da etinilestradiol düzeylerini azaltabileceğini savunan klinik raporlar mevcuttur. Kullanım şekli ve dozu: Kullanım: Tabletler paketin üstünde gösterildiği yönde, hergün yaklaşık aynı zamanda bir miktar suyla alınmalıdır. Birbirini izleyen 21 gün boyunca hergün bir tablet alınır. Her bir sonraki pakete 7 günlük, sıklıkla çekilme kanamasının izlendiği, tablet alınmayan dönem tabaklen geçilir. Bu kanama genellikle son tabletin alınması takiben 2.-3. gün başlar ve bir sonraki pakete başlandığında kesilmez. Eğer kullanıcı tabletini almakta 12 saatten daha az geç kalırsa, kontraseptif koruyuculuk azalmaz. Hatırlanmaz hatırlanmaz tablet alınmalı ve bir sonraki tabletler de her zamanki gibi alınmaya devam edilmelidir. Eğer 12 saatten daha fazla gecikme olmuşsa kontraseptif koruyuculuk azalmış olabilir. Mide-bağırsak bozuklukları durumunda: Şiddetli gastrointestinal bozuklukların olması durumunda emilim tam olmayabilir ve ek kontraseptif önlemler alınmalıdır. **Ticari taktim şekli:** PVC/Aluminyum blister de 63 (3x21) adet film kaplı tablet. **Ruhsat tarihi:** 20.02.2002, **Ruhsat no:** 111/87, **Ruhsat sahibi:** Bayer Türk Kimya San. Ltd. Şti., Fatih Sultan Mehmet Mah. Balkan Cad. No:53 34770 Ümraniye - İstanbul Tel: (0216) 528 36 00 Faks: (0216) 538 37 40 Reçete ile satılır. 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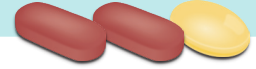
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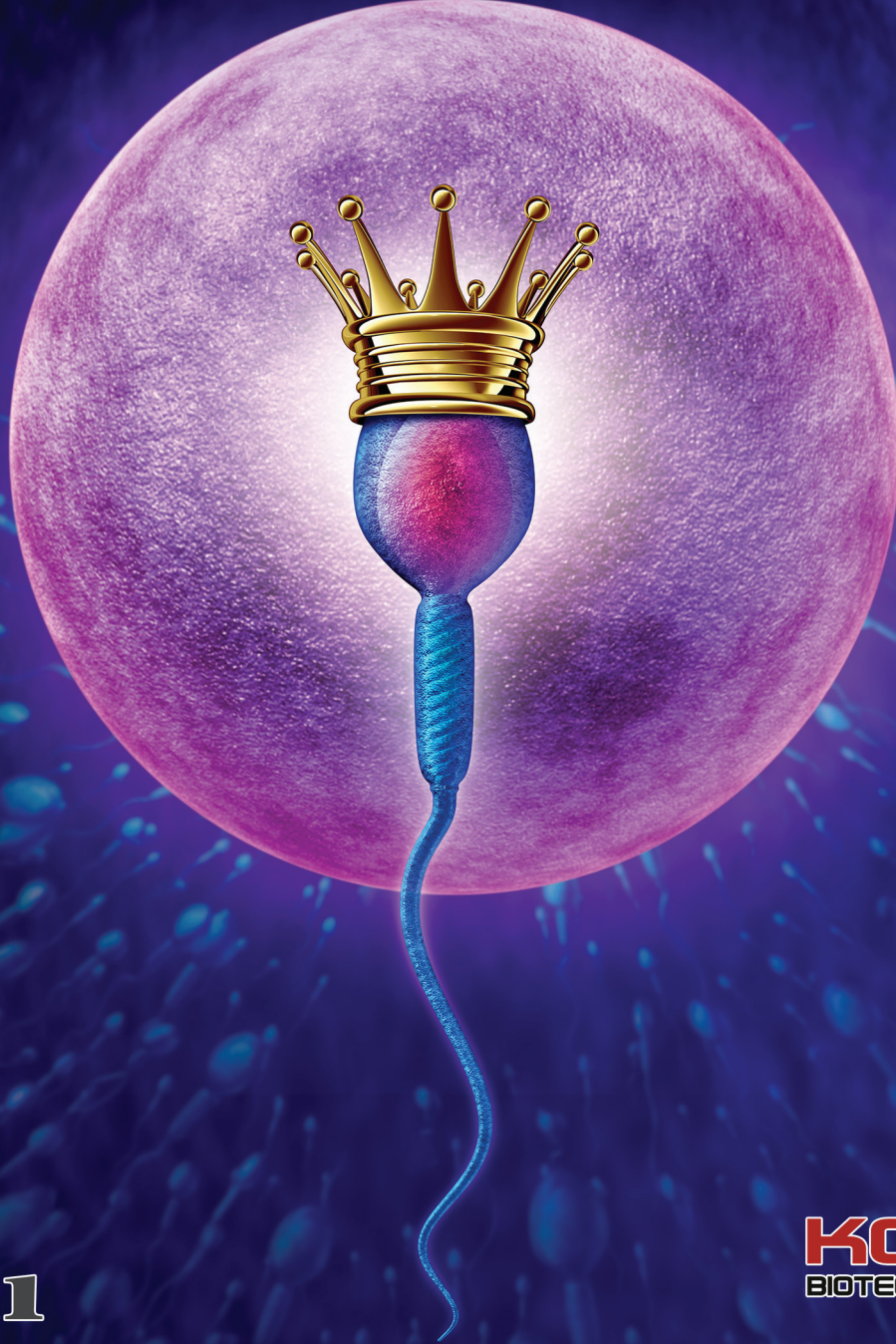
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