제101, 102차 P&T 통과약물 (2005. 6.14/7.19)

<table>
<thead>
<tr>
<th>No</th>
<th>약품명</th>
<th>함량/제형</th>
<th>상품명</th>
<th>약효별분류</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acyclovir</td>
<td>80 mg/ml, 150 ml/bottle</td>
<td>Zinacid</td>
<td>08:20 Antivirals</td>
</tr>
<tr>
<td>2</td>
<td>Agio®</td>
<td>6 g/package granule</td>
<td>Agio</td>
<td>56:28 Cathartics and Laxatives</td>
</tr>
<tr>
<td>3</td>
<td>Chlorhexidine gluconate/Ethyl alcohol</td>
<td>1%/61%, 500 ml/bottle</td>
<td>Avagard</td>
<td>38:00 Disinfectants</td>
</tr>
<tr>
<td>4</td>
<td>Diacerein</td>
<td>50 mg/capsule</td>
<td>Artrodar</td>
<td>92:00 Unclassified Therapeutic Agents</td>
</tr>
<tr>
<td>5</td>
<td>Hyaluronic acid</td>
<td>1,500 IU/ampule</td>
<td>H-lase</td>
<td>44:00 Enzymes</td>
</tr>
<tr>
<td>6</td>
<td>Imiquimod</td>
<td>50 mg/g, 5 g/package cream</td>
<td>Aldara</td>
<td>84:28 Keratolytic Agents</td>
</tr>
<tr>
<td>7</td>
<td>Levedopa/Carbipoda/Entacapone</td>
<td>50/12.5/200 mg/tablet</td>
<td>Stalevo</td>
<td>28:92 Miscellaneous Central Nervous System Agents</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100/25/200 mg/tablet</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>150/37.5/200 mg/tablet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Nomegestrol acetate</td>
<td>5 mg/tablet</td>
<td>Lutrenyl</td>
<td>68:16 Progestins</td>
</tr>
<tr>
<td>9</td>
<td>Pantoprazole</td>
<td>40 mg/tablet</td>
<td>Pantoloc</td>
<td>56:24.08 Proton Pump Inhibitors</td>
</tr>
<tr>
<td>10</td>
<td>Pirotelir tartrate</td>
<td>0.5 mg/1 ml/ampule</td>
<td>Preline</td>
<td>36:12 Pituitary Function</td>
</tr>
<tr>
<td>11</td>
<td>Telmisartan/</td>
<td>40/12.5 mg/tablet</td>
<td>Pritor Plus</td>
<td>24:04.14 Angiotensin II Receptor Antagonists</td>
</tr>
<tr>
<td>12</td>
<td>Hydrochlorothiazide</td>
<td>80/12.5 mg/tablet</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 mg, 40 mg/capsule</td>
<td>Zeldox</td>
<td>28:16.08 Tranquilizers</td>
</tr>
</tbody>
</table>

* 세부 약물정보 내용은 아래를 참조하여 주시기 바랍니다.

S6:28 Cathartics and Laxatives

**Agio®**

6 g/Package Granule

성분   1포 중 작전자(Plantago Seed) 3.9 g + 작전자피(Ispaghula Husk) 0.13 g
약리기전   정내 수분과 결합하여 장내물의 부피를 증가시키는 bulk형 제제
작용강도   
  · 진류 심유소가 부족한 경우의 장 정상화
  · 과인성대장증후군, 계실질환, 장질, 항문염증에 관련된 변비의 보조요법
  · 단순성, 만성, 경련성 변비의 치료
  · 변성, 고혈압, 노년기 변비에 사용하는 변비의 치료
용법   섭시 알고 몸 1-2입과 함께 복용
  · 성인 및 12세 이상의 소아 : 1회 1-2포, 저녁식후, 필요시 아침식전에 1포 추가
  · 소아(7-11세) : 1회 1포, 1일 1-2회
이상반응   심한 복통, 설사, 구토, 드물게 알레르지 반응
참고문헌   제약회사 자료
92:00 *Unclassified Therapeutic Agents*

### Diacerein

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50 mg/Capsule</td>
</tr>
<tr>
<td>약리기전</td>
<td>개최시나 무속 식물에 함유된 anthraquinone의 일종인 diacerein (항성 대사체: rhein)이 중동도의 혈관증, 경통효과 및 약한 사례에서 효과를 나타낸. 또한 단백구의 interleukin-18의 생성억제 및 인플로세포에 대한 cytokine의 작용을 저하함.</td>
</tr>
<tr>
<td>작용중</td>
<td>교관장염, 관절염, 관절염, 관절염의 치료</td>
</tr>
<tr>
<td>용법</td>
<td>종사에 따라 1-2개월간 1일 1-2회 투여하여 식후투여</td>
</tr>
<tr>
<td>약용학</td>
<td>1. 호수: BA 35-56%, 최고 종류 농도 도달 24시간(공복시), 5.2시간(식중 투여시) 2. 용도: 단백질합 99%(rhein), 부종용 13.2 L, 백합기 7-8시간(rhein) 3. 특성: 건강 복용 후 전신 순환기 전에 본 100%가 항성 대사체인 rhein으로 전환</td>
</tr>
<tr>
<td>활성 대사체(rhein glucuronide, rhein sulfite)</td>
<td>4. 배설: 노(35-60% : 20%-free rhein, 80%-conjugates of rhein)</td>
</tr>
<tr>
<td>이상반응</td>
<td>목, 인후, 실내, 자갈혈합증</td>
</tr>
<tr>
<td>소화기계</td>
<td>식사(37%, 최종 복용 2주 후에 사라짐), 급성 간염</td>
</tr>
<tr>
<td>요로/비뇨기계</td>
<td>능 빈혈(14.4%)</td>
</tr>
<tr>
<td>피부</td>
<td>표피 피사(Lyell's syndrome)</td>
</tr>
<tr>
<td>참고문헌</td>
<td>CCIS/Drugdex, 제약회사 자료</td>
</tr>
</tbody>
</table>

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84:28 *Keratolytic Agents*

### Imiquimod

<table>
<thead>
<tr>
<th></th>
<th>50 mg/g, 5 g/Package Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>약리기전</td>
<td>immune response modifier로 interferon-alpha와 같은 cytokine 분비를 유도한다는 보고가 있으나 기전은 불명확함.</td>
</tr>
<tr>
<td>작용중</td>
<td>성인의 외부 사용시, 항문주위 사마귀/결제 혼합로마의 치료</td>
</tr>
<tr>
<td>용법</td>
<td>주 3회 정상 수면시간 전에 병소에 바르고 6-10시간 후 부드러운 비누와 물로 병소를 씻어 본 제품을 제거함.</td>
</tr>
<tr>
<td>약용학</td>
<td>치료는 생성기 및 배변주위 사마귀가 완전히 사라질 때까지 행하며 최대 16주를 넘지 않도록 함.</td>
</tr>
<tr>
<td>1. 화수: 피로체는 거의 호수되지 않음.</td>
<td></td>
</tr>
<tr>
<td>2. 배설: 노(0.9%), 변(0.9%)</td>
<td></td>
</tr>
<tr>
<td>이상반응</td>
<td>중추신경계: 두통</td>
</tr>
<tr>
<td>소화기계</td>
<td>식사</td>
</tr>
<tr>
<td>요로/비뇨기계</td>
<td>동중, 충혈, 배뇨곤란</td>
</tr>
<tr>
<td>피부</td>
<td>혈관, 미란, 화상, 피부부락, 부종(혼합)</td>
</tr>
<tr>
<td>근골격계</td>
<td>근육통, 드립 유사 증후군</td>
</tr>
<tr>
<td>임부</td>
<td>FDA pregnancy category B</td>
</tr>
<tr>
<td>참고문헌</td>
<td>CCIS/Drugdex, 제약회사 자료</td>
</tr>
</tbody>
</table>

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68:16 *Progestins*

### Nomegestrol acetate

<table>
<thead>
<tr>
<th></th>
<th>5 mg/Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>약리기전</td>
<td>a synthetic progestin (19-norpregesterone derivative)</td>
</tr>
<tr>
<td>작용중</td>
<td>호르몬기능부전으로 인한 부인과적 징조</td>
</tr>
<tr>
<td></td>
<td>질병 또는 주기장애: 2차성 무성징, 이소성징, 이성정, 복합폐경기 시기의 기능성 자궁 출혈</td>
</tr>
<tr>
<td></td>
<td>자궁능력비후, 엉덩관부증후군, 실질관부증, 유방증</td>
</tr>
<tr>
<td></td>
<td>재연기 후 치료(에스트로겐과 병용하여 그 작용의 균형을 유지할 목적으로 사용)</td>
</tr>
<tr>
<td>용법</td>
<td>1일 5mg, 통상 매 주의 10일부터 25일까지 10일간 투여</td>
</tr>
</tbody>
</table>
56:24.08 Proton Pump Inhibitors

Pantoprazole 40 mg/Tablet

약리기전  a gastric proton pump (H+/K+ ATPase) inhibitor

작용중
  • *H. pylori* 감염된 위, 심장장기양의 재발 방지를 위한 항생제 병용요법
  • 위궤양, 심장장기양, 중등도-중증의 역류성 식도염
  • 줄리거혈관장증후군(Zollinger-Ellison Syndrome)과 기타 병리학적 위암 과반분 상태

용법
  • *H. pylori* (-) 위궤양장기 억제 재발방지를 위한 항생제 병용요법: 1회 40 mg, 1일 2회 아침저녁 식전, 1주간 복용
  • 복용시에도 치료효과가 충분하지 않은 경우 단독투여 가능
  • 위궤양 및 역류성 식도염: 1일 1회 40 mg, 치료기간 4주 (필요시 4주 연장)
  • 심장장기양: 1일 1회 40 mg (타제내성 1일 1회 80 mg)을 아침식전에 병거나 부수지 말고 물과 함께 복용.
  • 치료기간은 2주(필요시 2주 연장)

약동학
1. 혈주: BA 77%, 최고 혈중 농도 도달 2.8시간
2. 분포: 단백결합율 98%, 림프조직 0.17 L/kg, 반감기 1시간
3. 대사: 간(대부분 CYP2C19, CYP3A4)
4. 배설: 복(71-82%), 변(18-20%)

이상반응
  • 혈액계: 호산구증가증
  • 심혈관계: 말초 부종(가역적)
  • 중추신경계: 두통(1.3%), 기은고(0.7%), 후지증
  • 내분비계: 발열, 부종, 고혈당
  • 소화기계: 오심, 구토, 복부, 설사(4%)
  • 요장/비뇨기계: 혈뇨, 발기부진
  • 호흡기계: CAV 감염 빈도 증가
  • 신장기계: 시력 장애(사라 호리짐)
  • 피부: 발진, 소양증, 호포증, 광싱성 발진

임부
FDA pregnancy category B

참고문헌
CCIS/Drugdex, 제약회사 자료

28:16.08 Tranquilizers

Ziprasidone 20 mg, 40 mg/Capsule

약리기전  a benzothiazolyl piperazine derivative of atypical antipsychotic agents
  • serotonin 5HT2A/dopamine D2 antagonist, 5HT6 agonist
  • moderate-to-low affinity for  serotonin 5HT2A receptor (inhibits norepinephrine reuptake)

적응증  정신분열증의 치료
현시약물정보

- 정신병성 양상이 수반되는 혹은 수반되지 않은 양극성 장애와 관련된 급성 조절 혹은 혼예 잠하의(episode)의 치료

용법
- 정신 분열증의 치료
  - 금성 : 1회 40 mg, 1일 2회 음식과 함께 복용(max. 80 mg, 1일 2회)
  - 유지 : 1회 20 mg, 1일 2회
- 양극성 장애와 관련된 급성 조절 혹은 혼예 잠하의 치료
  - 1일에 1회 40 mg을 1일 2회 음식과 함께 복용
  - 2일째에 1회 60 mg 혹은 80 mg까지 증량하여 1일 2회 복용
- 이후 내약성 및 효능에 따라 1회 40-80 mg 복용 내에서 조절하여 1일 2회 복용

약동학
1. 흡수 : BA 60%, 최고 혈중 농도 도달 4-5시간, 최고 반응 도달 4주
2. 분포 : 단백결합률 ≥99%, 분포용적 0.5 L/kg, 반감기 7시간
3. 대사 : 간(CYP3A4), 활성대사체(ziprasidone sulfoxide)
4. 배설 : 녹(≤1%), 변(55%)

이상반응
- 심혈관계 : QT 간격 증가(dose-related), 기립성 저혈압, 반맥
- 중추신경계 : 정상신경중증, 자발성 운동장애, 피진선명 증상, 발작(0.4%), 두통, 불면증, 추체외로 중상(4%)
- 내분비/대사계 : 프로락틴 증가, 항정신병 약물 억제 중추증후군(NMS), 체중증가(0.4%)
- 소화기계 : 비변, 소화불량, 오심, 구토, 식욕부진
- 요로계/뇨기계 : 지속 발작기
- 간 : 간 효소 증가
- 전반계 : 근육 운동 반작
- 호흡기계 : 비염
- 피부 : 발진(3%), 진균성 피부염(1%)
- 근골격계 : 근육통(1%)

입부
- FDA pregnancy category C

참고문헌
- CCIS/Drugdex, 제약회사 자료

Are brand-name and generic warfarin interchangeable?

Warfarin is a commonly used anticoagulant in North America. Several generic formulations have been approved, raising concern over the safety and efficacy of these products compared with brand-name Coumadin. They tried to ensure that generic warfarin products can be safely interchanged with Coumadin. They conducted multiple n-of-1 randomized, double-blind, crossover trials switched outpatients (N=7) between a generic warfarin formulation (Apo-warfarin) and Coumadin over 30 weeks. Study patients took each drug for five 3-week periods, with international normalized ratio (INR) measurements taken twice per period. Inter- and intrapatient differences between generic warfarin and Coumadin were compared, and overall study patient results were compared with those of a Coumadin control group. There were no differences between warfarin products in terms of mean INR results or number of dosage adjustments required. There also was no difference in INR variation based on warfarin formulation (p>0.69), nor was a patient and warfarin interaction found (p=0.81). The INR results were not influenced by whether patients were maintained on Coumadin only (control group) or interchanged between Coumadin and generic warfarin (p=0.98). It appears that patients can safely and effectively switch between generic warfarin and Coumadin.


Selective serotonin-reuptake inhibitors in the treatment of premature ejaculation

They reviewed the use of selective serotonin-reuptake inhibitors (SSRIs) in the treatment of premature ejaculation. Articles were retrieved through a MEDLINE search (1966–Jan. 2004). Search terms used to identify articles included serotonin uptake inhibitors, premature ejaculation, rapid ejaculation, and sexual behavior, as
well as the generic names of currently available SSRIs: fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, and escitalopram. The literature search was limited to articles published in the English language containing human subjects. Articles obtained through the literature search were evaluated, and randomized controlled trials were included in this review. Information from noncontrolled trials or case reports was considered for inclusion if it contributed to the completeness of this review and if it was the highest level of evidence available. Premature ejaculation is a commonly reported sexual difficulty. Delayed ejaculation is a widely reported sexual adverse effect of SSRIs. In some men exhibiting premature ejaculation, the ability of the SSRIs to delay ejaculation has been therapeutic. Trials evaluating the ejaculation-delaying ability of SSRIs demonstrated that paroxetine, fluoxetine, sertraline, and citalopram produce a statistically significant increase in the ejaculation latency time compared with placebo. Taking advantage of the ejaculation-delaying effects of SSRIs increases the treatment options available to prescribers and patients. Convenience and minimal adverse effect profile make these agents an alternative to previously used behavior modalities and older pharmacologic agents. Although some questions still surround the details of their use, SSRIs have the potential to improve the quality of life for men with premature ejaculation and their partners.

*The Annals of Pharmacotherapy 2005;39:1296-301*

**Venous thromboembolism prevention in acutely ill nonsurgical patient**

They reviewed recent advances in the prevention of venous thromboembolism (VTE) in acutely ill nonsurgical inpatients. A MEDLINE search (1966–Mar. 2005) was done to identify relevant articles relating to prevention of VTE in acutely ill nonsurgical inpatients. Four major prophylaxis trials, one registry, one guideline, and supporting articles representative of the subject matter from the last few years were included. Enoxaparin, dalteparin, fondaparinux, and unfractionated heparin 5000 units every 8 hours are effective in reducing the risk of VTE in acutely ill medical patients, but such prophylaxis is currently underused. Barriers to be overcome include recognition of the importance of VTE in this population, definition of the optimal strategy to assess risks, optimal timing of the risk assessment, optimal prophylactic regimen for a given level of risk or disease state, and optimal duration of prophylaxis. They recommend that acutely ill medical inpatients should be risk-stratified early in their hospitalization. At this time, the specific risk-assessment protocol should be derived from the trial(s) of the available formulary agent(s). Decisions about providing prophylaxis must also be made considering anticoagulant contraindications and renal function. Mechanical methods of prophylaxis should be considered as monotherapy only if an anticoagulant contraindication exists. The optimal duration of prophylaxis is not known, but 14 days was used in recent studies. Prophylaxis of VTE in acutely ill medical inpatients is underused. Data provide some guidance for increasing awareness and optimizing patient care.

*The Annals of Pharmacotherapy 2005;39:1318-24*

**Childhood vaccination and nontargeted infectious disease hospitalization**

It has been hypothesized that multiple-antigen vaccines, such as measles-mumps-rubella vaccine, or aggregated vaccine exposure could lead to immune dysfunction, resulting in nontargeted infectious diseases as a result of an "overload" mechanism. They evaluated the relationship between routinely administered childhood vaccines (Haemophilus influenzae type b; diphtheria-tetanus-inactivated poliovirus; diphtheria-tetanus-acellular pertussis-inactivated poliovirus; whole-cell pertussis; measles-mumps-rubella; oral poliovirus) and hospitalization for nontargeted infectious diseases. They constructed population-based cohort comprising all children born in Denmark from 1990 through 2001 (N=805,206). Longitudinal information was collected on type and number of vaccine doses received and hospitalization with infectious diseases, specifically acute upper respiratory tract infection, viral and bacterial pneumonia, septicemia, viral central nervous system infection, bacterial meningitis, and diarrhea. The primary outcome was the rate ratios for each type of infectious disease according to vaccination status. During 2,900,463 person-years of follow-up, 84,317 cases of infectious disease hospitalization were identified. Out of 42 possible associations (6 vaccines and 7 infectious disease categories), the only adverse association was for Haemophilus influenzae type b vaccine and acute upper respiratory tract infection (rate ratio, 1.05; 95% confidence interval, 1.01-1.08 comparing vaccinated participants with unvaccinated participants). This one adverse association of 42 possible outcomes was within the limits of what would be expected by chance alone and the effect was not temporal or dose-response. When considering aggregated vaccine exposure, they found no adverse associations between an increasing number of vaccinations and infectious diseases. These results do not support the hypotheses that multiple-antigen vaccines or aggregated vaccine exposure increase the risk of nontargeted infectious disease hospitalization.

*JAMA 2005;294:699-705*

**Insulin resistance and risk of congestive heart failure**

Diabetes and obesity are established risk factors for congestive
heart failure (CHF) and are both associated with insulin resistance. They explored if insulin resistance may predict CHF and may provide the link between obesity and CHF. This study was based on The Uppsala Longitudinal Study of Adult Men, a prospective, community-based, observational cohort in Uppsala, Sweden. They investigated 1,187 elderly (70 years) men free from CHF and valvular disease at baseline between 1990 and 1995, with follow-up until the end of 2002. Variables reflecting insulin sensitivity (including euglycemic insulin clamp glucose disposal rate) and obesity were analyzed together with established risk factors (prior myocardial infarction, hypertension, diabetes, electrocardiographic left ventricular hypertrophy, smoking, and serum cholesterol level) as predictors of subsequent incidence of CHF, using Cox proportional hazards analyses. The primary outcome was the first hospitalization for heart failure. One hundred four men developed CHF during a median follow-up of 8.9 years (range, 0.01-11.4 years). In multivariable Cox proportional hazards models adjusted for established risk factors for CHF, increased risk of CHF was associated with a 1-SD increase in the 2-hour glucose value of an oral glucose tolerance test (hazard ratio [HR], 1.44; 95% confidence interval [CI], 1.08-1.93), fasting serum proinsulin level (HR, 1.29; 95% CI, 1.02-1.64), body mass index (HR, 1.35; 95% CI, 1.11-1.65), and waist circumference (HR, 1.36; 95% CI, 1.10-1.69), whereas a 1-SD increase in clamp glucose disposal rate decreased the risk (HR, 0.66; 95% CI, 0.51-0.86). When adding clamp glucose disposal rate to these models as a covariate, the obesity variables were no longer significant predictors of subsequent CHF. Insulin resistance predicted CHF incidence independently of established risk factors including diabetes in our large community-based sample of elderly men. The previously described association between obesity and subsequent CHF may be mediated largely by insulin resistance.

JAMA 2005;294:334-41

Hydroxyurea compared with anagrelide in high-risk essential thrombocythemia

They conducted a randomized comparison of hydroxyurea with anagrelide in the treatment of essential thrombocythemia. A total of 809 patients with essential thrombocythemia who were at high risk for vascular events received low-dose aspirin plus either anagrelide or hydroxyurea. The composite primary end point was the actuarial risk of arterial thrombosis (myocardial infarction, unstable angina, cerebrovascular accident, transient ischemic attack, or peripheral arterial thrombosis), venous thrombosis (deep-vein thrombosis, splanchic-vein thrombosis, or pulmonary embolism), serious hemorrhage, or death from thrombotic or hemorrhagic causes. After a median follow-up of 39 months, patients in the anagrelide group were significantly more likely than those in the hydroxyurea group to have reached the primary end point (odds ratio, 1.57; 95% CI, 1.04 to 2.37; P=0.03). As compared with hydroxyurea plus aspirin, anagrelide plus aspirin was associated with increased rates of arterial thrombosis (P=0.004), serious hemorrhage (P=0.008), and transformation to myelofibrosis (P=0.01) but with a decreased rate of venous thromboembolism (P=0.006). Patients receiving anagrelide were more likely to withdraw from their assigned treatment (P=0.001). Equivalent long-term control of the platelet count was achieved in both groups. Hydroxyurea plus low-dose aspirin is superior to anagrelide plus low-dose aspirin for patients with essential thrombocythemia at high risk for vascular events.

Comparing the risk for death with peritoneal dialysis and hemodialysis in a national cohort of patients with chronic kidney disease

The influence of type of dialysis on survival of patients with end-stage renal disease (ESRD) is controversial. To compare the risk for death among patients with ESRD who receive peritoneal dialysis or hemodialysis, they conducted a national prospective cohort study. From Oct. 1995 to Jun. 1998, 1,041 participants from 19 U.S. states were enrolled at 81 dialysis clinics (274 patients receiving peritoneal dialysis and 767 patients receiving hemodialysis). Patients were followed for up to 7 years and censored at transplantation or loss to follow-up. Cox proportional hazards regression stratified by clinic was used to compare the risk for death with peritoneal dialysis versus hemodialysis. Twenty-five percent of patients undergoing peritoneal dialysis and 5% of hemodialysis patients switched type of dialysis. After adjustment, the risk for death did not differ between patients undergoing peritoneal dialysis and those undergoing hemodialysis during the first year (relative hazard, 1.39 [95% CI, 0.64 to 3.06]), but the risk became significantly higher among those undergoing peritoneal dialysis in the second year (relative hazard, 2.34 [CI, 1.19 to 4.59]).

After stratification, the survival rate was no different for patients who had the highest propensity of being initially treated with peritoneal dialysis. Results were consistent with adjustment based on a propensity score model and in sensitivity analyses that used as-treated models and models in which switches in type of dialysis were treated as treatment failures. Results were similar but stronger in analyses that were restricted to patients who were treated only in clinics offering both types of dialysis. Patients were not randomly assigned to their initial type of dialysis. Also, more patients undergoing peritoneal dialysis than hemodialysis switched type of dialysis over time, and the reason for switching was often a consequence of the technique. The risk for death in patients with ESRD undergoing dialysis depends on dialysis type. Further studies are needed to evaluate a possible survival benefit of a timely change from peritoneal dialysis to hemodialysis.

Annals of International Medicine 2005;143:174-83

Pharmacokinetic changes of irinotecan by intestinal alkalization in an advanced colorectal cancer patient

The prevention of irinotecan (CPT-11)-induced diarrhea, a well-known adverse reaction to the drug, by treatment with intestinal alkalization has been carried out in patients with colorectal cancer in Japan. Under acidic conditions, CPT-11 and its active metabolite, SN-38, exists preferably as the lactone form, whereas both exist as the carboxylate form under basic conditions. It has been suggested that the lactone forms of both CPT-11 and SN-38 are diffused passively across the intestinal mucosal membranes, whereas the carboxylate forms are actively transported. The intestinal uptake rate of both forms appears to be pH sensitive under physiological conditions, but it remains unclear whether intestinal alkalization treatment affects the pharmacokinetics of CPT-11 and SN-38. This study was designed to evaluate the pharmacokinetics of CPT-11 and SN-38 in a colorectal cancer patient with or without alkalization treatment. They found that intestinal alkalization significantly decreased the plasma levels of CPT-11 and SN-38. In particular, the AUC of SN-38 was markedly decreased to 56 from 107 ng·h/mL. Intestinal alkalization was effective in preventing CPT-11-induced diarrhea, but this treatment changed the pharmacokinetics of CPT-11 and SN-38 in the body.

Ther Drug Monit 2005;27:536-8

Antibacterial activities of gemifloxacin, levofloxacin, gatifloxacin, moxifloxacin and erythromycin against intracellular Legionella pneumophila and Legionella micdadei in human monocytes

The antibacterial activity of a new fluoroquinolone, gemifloxacin, was tested against intracellular Legionella pneumophila and Legionella micdadei and was compared with the activities of levofloxacin, gatifloxacin, moxifloxacin and erythromycin. For intracellular assays, bacteria were used to infect human monocyte-derived macrophages prepared from heparinized blood of healthy volunteers. Antibiotics were added following phagocytosis. Numbers of viable bacteria were determined at 0, 24, 48, 72 and 96 h. The intracellular antibacterial activity of gemifloxacin was concentration- and time-dependent. All of the quinolones had similar activities against L. pneumophila and L. micdadei at 10 μg/mL, but there were minor differences: at 24 h moxifloxacin was significantly more active than the other quinolones against L. pneumophila, while gemifloxacin was more active against L. micdadei (P<0.01). All of the quinolones were markedly more active than erythromycin (P<0.01). The antibacterial effect of gemifloxacin against L. pneumophila following drug removal at 24 h persisted for 72 h at 20 μg/mL but not at 10 μg/mL, while for L. micdadei the antibacterial effect persisted for 24 h at 10 μg/mL. All of the quinolones had similar activities against intracellular L. pneumophila and L. micdadei and were markedly more effective than erythromycin.

J Antimicrobial Chemotherapy 2005;56:104-9

Long-term use of aspirin and nonsteroidal anti-inflammatory drugs and risk of colorectal cancer

Randomized trials of short-term aspirin use for prevention of
recurrent colorectal adenoma have provided compelling evidence of a causal relationship between aspirin and colorectal neoplasia. However, data on long-term risk of colorectal cancer according to dose, timing, or duration of therapy with aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) remain limited. They examined the influence of aspirin and NSAIDs in prevention of colorectal cancer. This study was based on the prospective cohort study of 82,911 women enrolled in the Nurses’ Health Study providing data on medication use biennially since 1980 and followed up through Jun. 1, 2000. The primary outcome was the incident colorectal cancer. Over a 20-year period, they documented 962 cases of colorectal cancer. Among women who regularly used aspirin (2 standard [325-mg] tablets per week), the multivariate relative risk (RR) for colorectal cancer was 0.77 (95% confidence interval [CI], 0.67-0.88) compared with nonregular users. However, significant risk reduction was not observed until more than 10 years of use (P<.001 for trend). The benefit appeared related to dose: compared with women who reported no use, the multivariate RRs for cancer were 1.10 (95% CI, 0.92-1.31) for women who used 0.5 to 1.5 standard aspirin tablets per week, 0.89 (95% CI, 0.73-1.10) for 2 to 5 aspirin per week, 0.78 (95% CI, 0.62-0.97) for 6 to 14 aspirin per week, and 0.68 (95% CI, 0.49-0.95) for more than 14 aspirin per week (P<.001 for trend). Notably, women who used more than 14 aspirin per week for longer than 10 years in the past had a multivariate RR for cancer of 0.47 (95% CI, 0.31-0.71). A similar dose-response relationship was found for nonaspirin NSAIDs (P=.007 for trend). The incidence of reported major gastrointestinal bleeding events per 1,000 person-years also appeared to be dose-related: 0.77 among women who denied any aspirin use; 1.07 for 0.5 to 1.5 standard aspirin tablets per week; 1.07 for 2 to 5 aspirin per week; 1.40 for 6 to 14 aspirin per week; and 1.57 for more than 14 aspirin per week. Regular, long-term aspirin use reduces risk of colorectal cancer. Nonaspirin NSAIDs appear to have a similar effect. However, a significant benefit of aspirin is not apparent until more than a decade of use, with maximal risk reduction at doses greater than 14 tablets per week. These results suggest that optimal chemoprevention for colorectal cancer requires long-term use of aspirin doses substantially higher than those recommended for prevention of cardiovascular disease, but the dose-related risk of gastrointestinal bleeding must also be considered.

*JAMA 2005;294:914-23*

**Statin therapy reduces contrast-induced nephropathy: An analysis of contemporary percutaneous interventions**

They sought to examine whether statin therapy before percutaneous coronary intervention results in reduction in contrast-induced nephropathy (CIN). Intravascular administration of contrast media can have nephrotoxic effects, particularly in patients with baseline renal insufficiency. Along with lowering serum cholesterol, statins have pleiotropic effects in the vasculature. The effect of statin use on CIN is unknown. They studied 29,409 patients who had both baseline preprocedure and peak postprocedure serum creatinine measured at the time of their percutaneous coronary intervention (PCI). Baseline demographics and creatinine profile before and after the procedure were compared between patients who received preprocedure statins and those who did not. CIN was defined as an increase in serum creatinine of ≤0.5 mg/dL. Baseline serum creatinine was similar between the two groups. When compared with patients who did not receive preprocedure statins, patients on preprocedure statins had a lower incidence of CIN (4.37 vs 5.93, P<0.0001) and nephropathy requiring dialysis (0.32 vs 0.49, P=0.03). After adjustments for comorbidities, preprocedure statin use was associated with a significant reduction in CIN (odds ration [OR] 0.87, 95% confidence interval [CI] 0.77-0.99, P=0.03). Preprocedure statin use is associated with significant reduction in CIN after contemporary PCI. This reinforces the need to initiate statin therapy before percutaneous coronary interventions.

*The American Journal of Medicine 2005;118:843-9*

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**FDA 승인약물**

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이약물안전성정보

Azithromycin  Persistent hiccups
인두염 치료를 위해 azithromycin을 복용하던 76세의 환자에서 지속적인 막막질이 발생되었다. 멸추지 않고 계속되는 막막질 에 환자는 기절한정한 지침에 이르렀다. 막막질을 유발하는 여 러 요인들을 평가한 후에도 별다른 원인을 발견할 수 없었으므 로 복용중인 azithromycin 두어를 중단하고 ibuprofen을 투여 한 후에는 환자의 막막질은 거의 정상되었다. 일반적으로 dexamethasone이나 methylprednisolone 등의 corticosteroids, midazolam 등 일부 benzodiazepines, 그리고 전신 마취제들에 혼합 복용은 아니지만 막막질을 유발하는 것으로 보고되고 있다. 그러나 macrolide 계 항생제들에 의한 막막질은 아주 드물게 보고되고 있다. Azithromycin과 막막질은 시간적인 긴밀한 관계가 있다. 다른 가능한 원인의 부재, 다르 르 macrolides에 의한 막막질에 대한 이전의 일부 보고 사례 등을 토대로 한 Naranjo scale에 가해서 점 5점으 로 possible한 관계를 나타내었다. Azithromycin의 발생위험성 막막질의 기존은 azithromycin이 미주신경염에서 주로 발생하는 것으로 추정된다. 저자들은 일반적으로 약물복용 및 막막질의 전반에 있어서는 아직 분명한 문제이며 단지 추정된 원인 아니라 제거하기 위한 방법을 이용해 이루어져고 있으나 이 환자의 경우는 macrolide 계 항생제의 복용과 관련 보고사례들이 존재하고, 미주신경염이 미치는 작용이 이런 부작용 발생에 대한 설명을 제공할 수 있어 더 명확히 진단할 수 있다고 주장했다.

J Clin Pharm Ther 2005; 30: 413-6

Zoledronic acid  Renal toxicity
Zoledronic acid 두어와 관련해 신부전이 발생한 사례가 최근 극적으로 보고되지 못했으나, 다른 나라에서는 아직 밝혀지지 않은 상황이다. 따라서 저자들은 프랑스에서 보고한 zoledronic acid 두어와 신독성과의 상관관계벽성을 위해 이상복용보고서 틀에 2004년 7월 1일까지 접수된 95개의 신부전사례 추적연구에 참여하였다. 보고된 12명의 환자 중 6명의 성별, 나이, 신기능, 임상적 특성에 따라 분석하였다. 환자 중 성별, 나이, 신기능, 임상적 특성에 따라 분석하였다. 환자 중 성별, 나이, 신기능, 임상적 특성에 따라 분석하였다. 약물 두어 후 1일째부터 3일째까지의 기간 동안 신부전이 발생한 경우, 즉 신기능 저하는 비교적 빠르게 나타났으며, 그중 1-2일일 때 가장 빠르게 나타났다. 이들 중 3명은 급성 신부전을 나타낸 반면, 다른 3명의 환자는 만성 신부전을 악화한 결과를 보였다. 신부전의 발생과 두어 후 발생한 환자 중 3명의 환자는 신부전 발생시 희망적 결과를 보았다. 이로 인해 이들 중 3명의 환자는 두어 후 신기능 저하가 보였으나, 다른 부분자들은 사망하거나 만성 신부전 상태로 남아있었다. 저자들의 논문에 따르면 신기능 저하가 발생할 경우 복용한 약물의 종류, 양도, 복용경로를 갖고 있어 신독성이 있는 다른 약물도 사용하는 환자에게 zoledronic acid 두어는 신독성을 일으키는 것으로 확인되었고 발전했다. 또한 zoledronic acid 두어는 기존 복용이 중단된 환자도 신장기능을 보다 복용해야하며 특히 이전에 신기능 저하가 있던 환자에게는 복용할 때 신기능 저하가 있을 것으로 예상되었다.


Sirolimus  Generalized, pruritic, ulcerating maculopapular rash
56세 코끼리같이 간세포환자에서 sirolimus사용과 관련된 반성성 태양의 외측 경계선이 호박받은 간이 발생했다. 환자의 증상은 면역억제제인 sirolimus를 중단하고 나서야 비로소 소실되었다. 저자들은 이와 관련된 최근 문헌들을 검토해 본 결과 sirolimus와 관련해서는 아주 드물게 유발되는 것으로 확인되었다고 밝혔다. Calcineurin계제제들의 사용으로 인해 신독성이 유발될 경우 면역억제제 대체제로 사용되고 있는 sirolimus는 큰 부작용이 없이 난소환자들은 좋은 내약성을 보여주고 있다. 일반적인 치료는 면역구강소감이나 항고인간 감소종, 흉부 지혈과 관련된 경우가 있다. 저자들은 기존의 복용에 대해 의결되어 있다. 이 환자에서 보이는 경계선이 호박받은 간성성 반점등구성의 발생이 sirolimus에 의한 것이라고 보고하였다.

Liver Transpl 2005; 11: 987-9

Levofloxacin  Acute fulminant hepatic failure
10년간 병원의 입상증상으로 호소하지 않았던 표현형양성 B형 간염을 가진 55세 여자환자에 갑작스런 간질의 증상을 위해 levofloxacin을 1일 500mg. 10일간 복용한 후 간질 후신자식의 복용을 주소로 내원하였다. 입원 후 혈청백혈구(PLA2)가 보저지고 요혈로 환자에 의한 복용이 회복되었다. 전격성 간염과 관련된 다른 방안들이 확인되자 환자에게는 이 환자의 같은 상황을 없으므로 결국 levofloxacin 유발전격성 간염이 가장 확실하다고 판단되어 약물 중단을 하였다. 이후 자동의 치료에도 불구하고 간질 육연능의 상태가 악화되어 내원 12주만에 사망하였다. 이 환자 간질성 간염의 levofloxacin 사용과의 관계 를 직접적인 인과관계벽성을 통해 정확한 결과가 확인된 결과가 나타났다. Levofloxacin은 항생제로 널리 사용되는 일반적인 약물로, 저자들은 복용을 통해 2005년 8월 현재 까지 이 약물로 인한 전격성 간염의 보고는 단 한 건이었다고 발표하였다. 또한 다른 병원의 혈액학적 환자는 없었다는 것과 약물복용과 짧은 복용기간, 그리고 약물에 의한 간염을 맞받침해 주는 병리학적인 자료들을 고려해 볼 때 이 환자의 levofloxacin과
Omeprazole  Interaction with calcium carbonate

65세 이상 여성 18명을 대상으로 omeprazole 20mg 또는 화약
매일 7일 동안 복용시키고 3주 후 휴약기간을 두고 교차하여 상
대편의 다른 약물로 진행하여 두어는 화자가약연구를 실시
하하였다. 두어 7일째 낮 아침에 의약품은 백제 복용 후 8시간간
으로 표시된 calcium carbonate를 섭취하였고 3일 및 5일째 후 체
혈을 통해 이러한 calcium carbonate의 혈중 수치를 측정하였다.
그 결과 calcium 홍수출 위반을 복용할 때 평균 9.1%,
omeprazole를 복용할 경우에 평균 3.5%로, omeprazole가 calcium
홍수출 위반하는 것으로 나타났다. 저자는 calcium이 pH가
낮을 때 가장 잘 용해되거나 proton-pump약제는 위의 pH를 증가
시켜 홍수출의 홍수출을 저해한다고 주장했으며 또한 인체가 어릴
게 감소된 calcium 홍수출에 적응할 수 있는지를 규명하고,
proton-pump약제와 calcium carbonate의 상호작용을 극복하는
기타 방법을 평가하는 추가 연구가 필요하다고 지적했다.

The American Journal of Medicine 2005:118:778-81

NSAIDs  Bleeding during periodontal surgery

저주 수술을 필요로 하는 의무 의료 인과 15명(남자 7명, 여자 8명)을
대상으로 수술 전에 ibuprofen을 복용한 그룹과 복용하지 않은
그룹으로 나누어 비교하였다. 그 결과 수술 전에 ibuprofen을
복용한 그룹은 그룹보다 수술 중 혈행
량이 2배 정도 많은 것으로 나타났다(31.93 ml vs. 17.80 ml). 특히
대비의 체계를 유도하는 수술의 경우에는 ibuprofen 사용군에서
혈행량이 보다 크게 증가되었다. 아울러 평균 출혈시간도
ibuprofen 사용군이 비 사용군에 비해 현저히 길 것으로 나타났
다(41.7 min vs. 38. min). Ibuprofen이 수술 중 동종 검증에 도움이
되었는가에 대한 실험 결과에서는 50%의 환자만이 정상적
으로 달성되었다. 저자는 적절 수술을 받기 전 동종 검증을 위해 사
용되는 ibuprofen은 동종 검증에 그다지 큰 효과를 나타내지 않
으며 실질적인 출혈의 위험을 증가시켜 수술을 받기 전에
ibuprofen의 사용을 중단해야 한다고 밝혔다.

J Periodontol 2005;76:1154-60

Isotretinoin  Revision of the label

FDA는 전문 의료인과 화자들에게 Accutane®과 generic
isotretinoin에 대해 강력한 위험 관리 프로그램인 PLEDGE를 승
인한다고 발표하였다. 이 프로그램은 isotretinoin을 축정, 처방,
조제, 사용하는 모든 과정에서 화자에게 대한 노출을 최소화하
기 위해 설계된 것으로, 이러한 프로그램은 각각의 의무를 이
행 할 드래프트자, 의사, 약사, 화자 및 환자의 등록이 필요하다.
FDA는 isotretinoin의 복용과 관련된 자살 및 사망 사례에 대한 보고
를 계속하여 학습하고 있다. 그 보고서에 살펴보면, isotretinoin
을 복용한 모든 화자는 수용증이나 자살에 대한 생각, 피곤증,
식약처에서 알림

위협한 증상, 문노, 사회활동에 대한 통증상, 수면증, 불면증, 
세증이나 식欲의 변화, 감정장애, 기억력영향, 공격성향 
등과 밀접한 증상이 나타날 수 있다는 것으로, 이러한 증상이 
나타나면 Isotretinoin 복용을 즉시 중단하고, 진료 의료인에게 
알려 추가적인 관리를 받아야 하는 것으로 되어 있다. 또한 
FDA는 환자나 임상의사들이 Isotretinoin을 사용하기 전후의 
병과 증상이나 수용성 증상의 위험을 더 면밀히 살피고 관리할 수 
있도록 각자의 제품설명서의 경고 부분을 변경하도록 조치했 
다.

http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Accurate

Sildenafil citrate, Tadalafil, Vardenafil HCl
Revision of the label

FDA는 전문 의료인들에게 sildenafil citrate (Viagra®), tadalafil (Cialis®), vardenafil HCl (Levitra®)의 제품설명서의 추가사항을 동 
보하였다. 이는 소수의 환자에서 감각기 시각이 감퇴되는 이상 
반응에 대한 사전 고보에 따른 것으로, 이러한 시각 감퇴는 
시신경의 혈류가 차단된 환경에서 발생하는 NAION (non 
arteritic ischemic optic neuropathy)에 기인한다. FDA는 환자들에게 
가능한 합병증이나 약물과의 상호작용을 감지하는 시각 감퇴가 
있으면 약물의 복용을 즉시 중단하고, 전문 의료인에게 알려 
한도하였다. 이 제품들은 복용 중인 환자나 복용하고 고려 
중인 환자들 중, NAION의 병력이 보이는 심각한 시각 감퇴

Fentanyl (transdermal patch)
Revision of the label

Janssen사와 FDA는 2005년 7월, fentanyl 패치제의 제품설명서 
내용을 변경하였다고 밝혔다.

이번 변경내용에는 결코, 급기, 주의사항, 용법 용량 부분의 
변경뿐만 아니라 다음과 같은 주요 사항의 변경사항 정보를 포 
함한다. 오름영구제대에서 사용하는 내용, CYP3A4 지배제제의 상호 
작용, 소양성성의 증가에 대한 내용, 빠른 투여에 대한 내용, fentanyl 
의 주의사항 노출된 경우, 만성 폐쇄성, 무증상성, 두개내압, 다른 CNS작 
용 항우울제와의 상호작용, 악몽이나 야간 잠의 소양성의 상호작 
용에 대한 내용 등을 담고 있다. 또한 FDA는 환자 및 환자보호 
자를 위한 안내지침을 발간하여 fentanyl 패치제의 사용안전 
및 위험에 대한 정보를 제공하기로 했다.

http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#drugs

의약품안전성정보

1. 신약임금 : 2005년 7월 1일 ~ 8월 31일 (12건)

<table>
<thead>
<tr>
<th>코드</th>
<th>약품명</th>
<th>상품명</th>
<th>제약회사</th>
<th>효능</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACYC-S</td>
<td>Acyclovir 80 mg/ml, 150 ml btl syrup</td>
<td>Zinacid</td>
<td>진상제약</td>
<td>항바이러스제</td>
</tr>
<tr>
<td>AG-1K</td>
<td>Acogluor pregranules 4.08 g, 6 g package granule</td>
<td>Agio</td>
<td>부평약품</td>
<td>번비 치료제</td>
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<tr>
<td>ILOPI</td>
<td>Iloprost 0.02 mg/ml/ea inhalation solution</td>
<td>Ventavis</td>
<td>한국생제</td>
<td>폐고혈압 치료제</td>
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<tr>
<td>PANTO</td>
<td>Pantoprazole 40 mg/tab</td>
<td>Pantoloc</td>
<td>탈강미약</td>
<td>소화성 폐가 치료제</td>
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<tr>
<td>SCZ-3C</td>
<td>Sertaconazole rtrate 20 mg/g, 30 g tube cream</td>
<td>Dermofix</td>
<td>부평약품</td>
<td>항진균제</td>
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<tr>
<td>XPIAB</td>
<td>Peginterferon β 50 mcg/vial</td>
<td>Pegintron</td>
<td>Schering-Plough/유한상호</td>
<td>만성 C형 간염 치료제</td>
</tr>
<tr>
<td>XPIAB7</td>
<td>Peginterferon β 80 mcg/vial</td>
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<tr>
<td>XPIAB7</td>
<td>Peginterferon β 100 mcg/vial</td>
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<tr>
<td>XPIAB7</td>
<td>Peginterferon β 120 mcg/vial</td>
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<tr>
<td>XRMI</td>
<td>Remifentanil 1 mg/vial</td>
<td>Ultiva</td>
<td>GSK</td>
<td>&quot;</td>
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<tr>
<td>XRMI2</td>
<td>Remifentanil 2 mg/vial</td>
<td>&quot;</td>
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<tr>
<td>XRMI5</td>
<td>Remifentanil 5 mg/vial</td>
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2. 완의/개방코드 (4종)

<table>
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<tr>
<th>코드</th>
<th>약품명</th>
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<th>제약회사</th>
<th>효능</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIACE</td>
<td>Diclofenac 50 mg/cap</td>
<td>Artrofor</td>
<td>의무재약</td>
<td>골관절염 치료제</td>
</tr>
<tr>
<td>NOME</td>
<td>Naloxone acetate 5 mg/tab</td>
<td>Lutynyl</td>
<td>삼일제약</td>
<td>황제기능부전으로 인한 부인과적 장애</td>
</tr>
<tr>
<td>PRITP</td>
<td>Telmisartan 40 mg Hydrochlorothiazide 12.5 mg/tab</td>
<td>Prior Plus</td>
<td>GSK</td>
<td>고혈압 치료제</td>
</tr>
<tr>
<td>PRITP8</td>
<td>Telmisartan 80 mg Hydrochlorothiazide 12.5 mg/tab</td>
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3. 제약회사 변경 (1종)

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<th>약품명</th>
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<th>제약회사</th>
<th>비고</th>
</tr>
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<tbody>
<tr>
<td>CLOM</td>
<td>Clofibric acid 50 mg/tab</td>
<td>Clofibric</td>
<td>미리먼제약 → 삼일제약</td>
<td>생산중단으로 인한 변경</td>
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4. 코드 locking (6종)

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<th>코드</th>
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<th>제약회사</th>
<th>비고</th>
</tr>
</thead>
<tbody>
<tr>
<td>INADO</td>
<td>Indomethacin 25 mg/cap SR</td>
<td>Inteban sparsule</td>
<td>의무재약</td>
<td>생산중단</td>
</tr>
<tr>
<td>PRZS</td>
<td>Prazosin 1 mg/tab</td>
<td>Minipress</td>
<td>한국화이자</td>
<td>생산중단</td>
</tr>
<tr>
<td>PRZS2</td>
<td>Prazosin 2 mg/tab</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>SCZ3-C</td>
<td>Sertaconazole nitrate 20 mg/g. 20 g/tube cream</td>
<td>Dermofix</td>
<td>부유약품</td>
<td>생산중단, SCZ3-C로 대체</td>
</tr>
<tr>
<td>XIMH28</td>
<td>Insulin (RI 20-NPH 80) 100 IU/ml, 3 ml/pen</td>
<td>NovoLet 20/80</td>
<td>&quot;</td>
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<tr>
<td>XIMHT3</td>
<td>Insulin (RI 30-NPH 70) 100 IU/ml, 3 ml/pen</td>
<td>NovoLet 30/70</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
</tbody>
</table>