December

Better Pharmacist Knowledge

Jordan Drug Information and Toxicology Centre 2025

2025

FDA Acts to Protect Children from Unapproved Fluoride Drug Products (November 2025)

The U.S. Food and Drug Administration (FDA) announced new measures to restrict the sale of unapproved ingestible fluoride prescription drugs intended for children. Notices were sent to four companies marketing such products for children under age three or for those at low or moderate risk of tooth decay. The FDA emphasized that these products have never been reviewed or approved for safety, effectiveness, or quality, despite decades of use. Recent scientific evaluations revealed potential risks, including negative effects on the gut microbiome and possible links to reduced IQ. While fluoride can reduce cavities in older children, evidence shows no significant benefit for baby teeth. The FDA advises against using unapproved ingestible fluoride drugs in children under three and in those not at high risk of tooth decay. To support healthcare professionals, FDA also issued a warning letter outlining these risks and announced plans, in collaboration with NIH and HHS, to develop a fluoride research agenda and a national oral health strategy to better address children's dental health [1]

Fish oil supplements for patients on maintenance dialysis (November 2025)

For patients on maintenance dialysis, we suggest fish oil supplements (Grade 2B) to prevent new and recurrent cardiovascular events. However, future trials to confirm benefit are warranted.

Patients on dialysis are at high risk of cardiovascular (CV) morbidity and mortality. In a trial in which over 1200 patients on maintenance hemodialysis were randomly assigned to either high-dose fish oil supplementation or placebo, the rate of serious CV events (ie, CV death, nonfatal myocardial infarction, nonfatal stroke, and peripheral vascular disease leading to amputation) was lower in the fish oil group during 3.5 years of follow-up (0.31 versus 0.61 per 1000 patient-days). The benefit in patients without a history of CV disease (approximately two-thirds of the study population) was similar to that in patients with such a history. However, **fish oil did not lead to a statistically significant reduction in all-cause mortality. Based on these data, we now suggest fish oil supplements for patients on maintenance dialysis.** [2]

Long-term antiplatelet therapy after percutaneous coronary intervention in patients taking oral anticoagulation (November 2025)

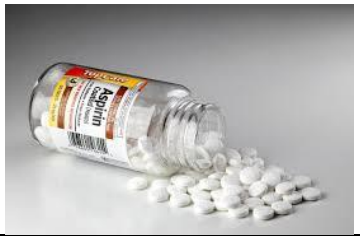
For most patients on long-term oral anticoagulant therapy, we now suggest not continuing antiplatelet therapy indefinitely (Grade 2B), and typically stop 6 to 12 months after percutaneous coronary intervention. However, for selected patients who are at very high risk of thrombotic events, it is reasonable to continue a single antiplatelet drug.

Patients with an indication for oral anticoagulation (OAC) who undergo percutaneous coronary intervention (PCI) often receive combination antithrombotic therapy (ie, OAC plus an antiplatelet medication) indefinitely; however, it is uncertain whether long-term antiplatelet therapy is necessary. Two recent trials addressed this question:

-A trial in over 800 patients with stent placement >6 months prior to enrollment and current treatment with long-term OAC found that participants randomly assigned to aspirin had higher rates of death and major bleeding compared with those assigned to placebo.

-A trial in over 900 patients with stent placement >12 months prior to enrollment found that patients randomly assigned to direct oral anticoagulant (DOAC) monotherapy had lower rates of a composite endpoint of death, myocardial infarction, stent thrombosis, stroke, systemic embolism, and clinically important bleeding compared with those assigned to combination therapy (DOAC plus clopidogrel); this difference was driven primarily by a reduction in bleeding.

For most patients on long-term OAC, we now suggest not continuing antiplatelet therapy indefinitely, and typically stop 6 to 12 months after PCI. However, for selected patients at very high risk of thrombotic events, it is reasonable to continue a single antiplatelet drug.[3]



References:

1. FDA Acts to Protect Children from Unapproved Fluoride Drug Products, accessed online via Contemporary Pediatrics, cited on 18th Dec, 2025.
2. Fish oil supplements for patients on maintenance dialysis, accessed online via uptodate , cited on 18th Dec, 2025.
3. Long-term antiplatelet therapy after percutaneous coronary intervention in patients taking oral anticoagulation, accessed online via uptodate , cited on 18th Dec, 2025.

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Oral nicotinamide for the chemoprevention of cutaneous squamous cell carcinoma (November 2025)

Previous studies have suggested that daily oral supplementation with nicotinamide (vitamin B3) may reduce the risk of subsequent cutaneous squamous cell carcinomas (cSCCs) in patients with a history of cSCC. In a large retrospective study using data from the United States Veterans Health Administration on nearly 34,000 patients with at least one previous cSCC, patients exposed to nicotinamide 500 mg twice daily had a 22 percent reduced risk of developing new cSCCs compared with those who were never exposed. The risk reduction was approximately 50 percent among patients who initiated nicotinamide after the diagnosis of their first cSCC and tended to decrease with the increasing number of previous cSCCs. Although these results appear promising, further studies are needed to evaluate the optimal dose, efficacy, and safety of long-term nicotinamide supplementation before it can be routinely recommended for the chemoprevention of cSCC.[1]

Safety of statin exposure during pregnancy (October 2025)

Animal studies have suggested that statins have teratogenic effects; however, whether there is a risk to human fetuses remains uncertain. In a Norwegian registry that included more than 800,000 pregnant patients, there was no significant association between first-trimester exposure to statins and congenital malformations. Individuals on statins who become pregnant may be reassured that the risk of congenital malformations is not increased. However, **statins should be stopped when pregnancy is recognized and avoided during pregnancy by most patients because they may increase the risk of spontaneous abortion and preterm labor**. [2]

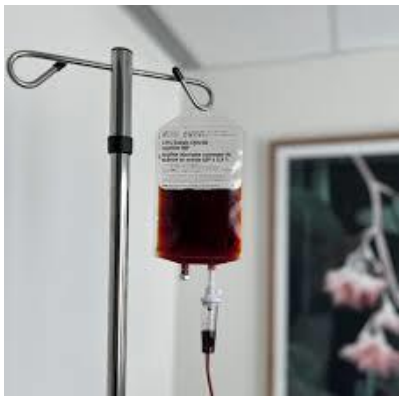
تعميم صادر عن المؤسسة العامة للغذاء والدّواء :

إشارة الى تقارير رصد الآثار الجانبية التلقائية الواردة إلى المؤسسة العامة للغذاء والدواء/مركز رصد الآثار الجانبية الأردني والتي تتضمن حدوث حالات (hypersensitivity reaction) بعد استخدام حقن iron dextran وحرصا من المؤسسة العامة للغذاء والدواء على تعزيز سلامة المرضى والحد من الآثار الجانبية المرتبطة بهذه المجموعة العلاجية والتي تشمل المستحضرات الصيدلانية المسجلة في المؤسسة وهي:

Generic name	Medicine Trade Name
Iron Dextran	**Cosmofer** 50mg/ml solution for infusion and injection
Iron Sucrose	**Venofer** 20mg/ml, solution for IV injection. **Ferrasil** 100mg/5ml, solution for IV injection. **Ferrovin** 20mg/ml, solution for IV injection. **Feradeed** 20mg/ml, solution for IV injection. **Feromax** 20mg/ml, solution for IV injection.
Ferric Carboxymaltose	**Ferinject** 500mg/10ml Solution for intravenous administration

وبناءا على ذلك نرجو اتباع التوصيات والارشادات التالية خلال استخدام المستحضرات الدوائية أعلاه:

- يجب التأكد في كل مرة يتم فيها اعطاء مستحضرات الحديد الوريدي من الاسم التجاري للمستحضر ونوع الحديد الذي يحتويه، والرجوع الى النشرة الداخلية المعتمدة للمستحضر لتحديد طريقة الاعطاء الصحيحة.
- جميع المستحضرات التي تحتوي على الحديد الوريدي قد تسبب تفاعلات تحسسية خطيرة.
- تشير البيانات الى أن التفاعلات التحسسية الخطيرة حتى لدى المرضى الذين لم تظهر لديهم أي تفاعلات سابقة بعد اعطائهم جرعة من الحديد الوريدي سابقاً.
- يجب اعطاء أدوية الحديد الوريدي فقط في أماكن مجهزة بطاقم طبي مدرب على تقييم وإدارة التفاعلات التأقية، مع توفر معدات الانعاش الفوري.
- يجب مراقبة المرضى أثناء جلسة اعطاء هذه المستحضرات الصيدلانية تحسباً لحدوث رد فعل تحسسي خلال أو بعد اعطاء هذه المستحضرات.
- في حال حدوث أي تفاعل تحسسي، يجب على الطبيب أو مقد الرعاية الصحية ايقاف اعطاء الحديد فوراً وبدء العلاج المناسب للتعامل مع ردة الفعل التحسسي.
- يمنع استخدام أدوية الحديد الوريدي لدى المرضى الذين لديهم حساسية معروفة لأي مكونات المستحضر (المواد الفعالة او المواد غير الفعالة).
- كما تود المؤسسة العامة للغذاء والدواء التنويه بأنها قد قامت بإصدار مادة تثقيفية بهذا الخصوص، موجهة إلى مقدمي الرعاية الصحية. [3]



References:

1. Oral nicotinamide for the chemoprevention of cutaneous squamous cell carcinoma, accessed online via uptodate , cited on 18th Dec, 2025.
2. Safety of statin exposure during pregnancy , accessed online via uptodate , cited on 18th Dec, 2025.
3. JFDA.(12/10/2025)

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