90 authorised drugs that are more dangerous than beneficial

As of early 2018, based on the drugs, examined by *Prescrire* between 2010 and 2017, that are authorised in France or in the European Union, 90 drugs were identified that are more dangerous than beneficial in all their authorised indications. 79 of these drugs are marketed in France (a,b).

They are listed below, based first on the therapeutic area in which they are used and then in alphabetical order of their international nonproprietary names (INNs).

These 90 drugs comprise:
- Active substances with adverse effects that, given the clinical situations in which they are used, are disproportionate to the benefits they provide;
- Older drugs that have been superseded by newer drugs with a better harm-benefit balance;
- Recent drugs that have a less favourable harm-benefit balance than existing options;
- Drugs that have no proven efficacy (beyond the placebo effect) but that carry a risk of particularly severe adverse effects.

The main reasons why these drugs are considered to have an unfavourable harm-benefit balance are explained in each case. When available, better options are briefly mentioned, as are situations (serious or non-serious) in which there is no suitable treatment.

The differences between this year’s and last year’s reviews are detailed in the inset below.

Review produced collectively by the Editorial Staff: no conflicts of interest  
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a- Four drugs mentioned in notes c, d, e, f are useful options when used in other forms or dosages than those presented in the text.
b- Nintedanib is mentioned twice in this review, in non-small cell lung cancer and idiopathic pulmonary fibrosis, but it was counted as one drug to be avoided.

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Notable changes in the 2018 update

Three drugs from *Prescrire*’s 2017 review of drugs to avoid are no longer available or no longer authorised: strontium ranelate, for osteoporosis, was withdrawn worldwide in mid-2017 by the pharmaceutical company that markets it (*Prescrire Int* n° 183); the *dexamethasone + salicylamide + hydroxyethyl salicylate* combination in sprains and tendinopathy (withdrawn by the company in France), and catumaxomab for malignant ascites (EU marketing authorisation withdrawn at the company’s request).

Canagliflozin and omalizumab: *Prescrire* reviewing new data in 2018. Some drugs listed in last year’s review of drugs to avoid, compiled in early 2017, have been dropped from this year’s review, pending the outcome of our reassessment of their harm-benefit balance. We are currently analysing new data published on canagliflozin, and because dapagliflozin has a similar mechanism, both drugs have been removed from this year’s update.

We are also re-examining the harm-benefit balance of the recombinant anti-IgE monoclonal antibody omalizumab in severe asthma; and because mepolizumab has a similar mechanism and similar adverse effects, this anti-interleukin-5 monoclonal antibody has also been removed from this year’s review.

Additions: metopimazine, nifuroxazide. We analysed the cardiac adverse effects of metopimazine in 2017. This neuroleptic of the phenothiazine class is commonly used in France as an antiemetic, and about 4 million patients in France were exposed to it in 2016, most of whom had gastroenteritis. The little data available show that it can provoke serious cardiac disorders (including syncope, arrhythmias and sudden death). These are unacceptable reactions for a drug taken to relieve transient nausea and vomiting (to be published in *Prescrire Int*, May issue).

Four other drugs have been added because their harm-benefit balance is unfavourable in all their approved indications: the intestinal “anti-infective” agent nifuroxazide; the fixed-dose combination conjugated equine oestrogens + bazedoxifene in menopausal symptoms; roflumilast for severe chronic obstructive pulmonary disease; and selexipag for pulmonary arterial hypertension.

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Selected references from Prescrire’s literature search

4- Prescrire Editorial Staff “Determining the harm-benefit balance of an intervention: for each patient” *Prescrire Int* 2014; 23 (154): 274-277.
5- Prescrire Editorial Staff “Treatment goals: discuss them with the patient” *Prescrire Int* 2012; 21 (132): 276-278.