boletim de FARMACOVIGILÂNCIA

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2019: key messages

- **BIOLOGICALS** The quality profile of biologicals is dynamic and varies depending on manufacture processes. Trademark names and batch numbers are essential for a correct assessment of cases of biological medicine associated adverse drug reactions. **BolFVG 3–2019**

INTERACTIONS

- **CAPECITABINE AND BRIVUDINE** Inhibition of brivudine's main metabolite leads to an increased therapeutic effect of capecitabine and therefore to increased serum levels of 5-fluorouracil. High concentrations of the latter can cause a range of adverse reactions, namely haematological and digestive, which can be fatal. Patients on capecitabine should wait 24 hours before they start taking brivudine. Conversely, in a patient already on brivudine, four weeks should elapse between its latest dose and the start of therapy with capecitabine. **BolFVG 2–2019**
- **BIOTIN (vitamin B7 or H)** Biotin can interfere with clinical lab tests based on the biotin/streptavidin interaction (e.g., troponin, thyroid function) giving rise to falsely decreased or increased results. Risk of interference is higher in children and in renally impaired patients, and increases for higher doses of biotin, namely single doses ≥ 150 µg (oral use) or ≥ 60 µg (parenteral use). **BolFVG 2–2019**

- **CONTRAST AGENTS** Contrast agents, namely intravascular, make up a group of medicines that is especially prone to medication errors. The Summaries of the Products' Characteristics (SmPCs) include dosages for an average adult weighing 70 kg. However, the dose to be administered should be the lowest necessary for the patient's actual weight. The product's solution should be warmed up to 37 degrees Celsius to reduce viscosity and minimize the occurrence of adverse reactions. The stated perfusion rate should be used. **BolFVG 4–2019**

Cont'd ▶

Portal RAM

Notificação de Reações Adversas a Medicamentos

Report an adverse drug reaction here.
Find answers to your questions about the ADR Portal here.

INDEX CARD

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2019: key messages

▶ *Cont'd*

FEMALE HORMONES

- **COMBINED ORAL CONTRACEPTIVES** The use of any combined oral contraceptive increases the risk of venous thromboembolism (VTE) compared to non-use and especially during the first year of use. Risk varies slightly among contraceptives and the lowest risk is found for those containing the progestogens levonorgestrel, norethisterone and norgestimate. Pregnancy and puerperium meanwhile, are associated with the greatest risk of VTE. **BolFVG 5–2019**

- **HORMONAL REPLACEMENT THERAPY (HRT)** The Collaborative Group on Hormonal Factors in Breast Cancer study has concluded that, compared to women who had never used HRT, women who did had approximately one case of breast cancer "too many" for every 50 women users. The lowest effective dose of HRT during the shortest possible period should be used and only as long as the benefit of menopause-associated symptoms exceeds the risks for each individual case. Benefits and risks should be weighed individually and periodically reviewed by the attending physician. Women who are using or have used HRT in the past should follow breast cancer screening and surveillance recommendations and seek their attending physician's advice for any doubt that may arise. **BolFVG 8–2019**

PREGNANCY

- **ANTIRHEUMATIC AGENTS** Effective drug therapy of active rheumatic conditions is possible during pregnancy with reasonable safety for the foetus. Disease activity control and pre-conceptional advice are necessary. EULAR (the European League Against Rheumatism) has issued consensus recommendations on the various drugs used in rheumatic conditions and their indications in pregnancy. **BolFVG 7–2019**

- **MODAFINIL** Although data concerning exposure to modafinil in pregnancy are limited, there is evidence suggesting a risk of congenital malformations in the foetus. Modafinil should therefore not be used in pregnancy and effective contraception should be ensured. **BolFVG 6–2019**

- **ONDANSETRON** Ondansetron should not be used in the first trimester of pregnancy, since it is suspected that it may cause orofacial malformations. **BolFVG 10–2019**

- **VALPROATE AND VALPROIC ACID** Given the risk of foetal malformations and childhood developmental problems, measures to avoid intrauterine exposure to these medicines have been reinforced, including new contraindications during pregnancy: migraine attack prophylaxis, bipolar disorder, and epilepsy treatment, except when no therapeutic alternative is available. **BolFVG 9–2019**

- **SPASTICITY** The treatment of spasticity should be multidimensional and include functional rehabilitation. It should be started with caution so as not to jeopardize previously established function. Drug therapy (oral, focal and intrathecal) has an important role in symptom control and the adverse effect profile of the most commonly used drugs should be adequately weighed in. **BolFVG 10–2019**

- **SGLT2 INHIBITORS** There may be an increased risk of toe amputation (mostly at first toe and metatarsal level) in patients on SGLT2 inhibitors. Risk minimization measures should always be borne in mind, especially in poorly controlled diabetics and/or in patients with high baseline cardiac or vascular risk. **BolFVG 11–2019**

- **FENSPIRIDE** Pneumorel® and Pneumorel retard® have been withdrawn from the market on account of a risk of potentially life-threatening arrhythmias, namely *torsades de pointes*. **BolFVG 7–2019**

Educational Materials published on the Infomed product information webpage

Click on the links.

INN Medicinal product	Target	Comunication Online publication date
Abacavir Abacavir Generis **Abacavir + Lamivudine** Abacavir + Lamivudina Aurovitas	**Physicians:** hospital infectious diseases and internal medicine department directors **Pharmacists:** hospital pharmaceutical service directors	Serious hypersensitivity reactions 13-12-2019
Adalimumab Humira	**Physicians and caregivers**	Paediatric patient safety card 09-12-2019
Axicabtagene ciloleucel Yescarta	**Healthcare professionals:** in multidisciplinary teams in qualified centres and in charge of managing patients on *Yescarta*	Handling and administration guide Guide on management of serious neurological adverse reactions and cytokine release syndrome 10-12-2019
Catridecacog NovoThirteen	**Physicians:** specialists in immunohaemotherapy at hospitals that are reference centres for congenital coagulopathies	Physician guide
	Patients	Patient guide 03-12-2019
Cemiplimab Libtayo	**Patients**	Alert card Patient guide 09-12-2019
Cerliponase alfa Brineura	**Healthcare professionals:** who prescribe or administer this medicine or who manage these patients (paediatricians, neuropaediatricians, internists or other physicians, nurses, psychologists and pharmacists) at centres specializing in the treatment of type 2 neuronal ceroid lipofuscinosis (CLN2)	Posology and administration guide 13-12-2019

Compiled by Patrícia Catalão

Farmacovigilância em Portugal: 25 anos E-book

Chapter 5.5. – Communicating with Citizens (Vanda Araújo)

Communicating risk to healthcare professionals and consumers is an essential risk minimization tool. Some information and communication media such as the Summary of the Product's Characteristics (SmPC) for healthcare professionals and the **Information Leaflet** for patients, are quite adequate from a regulatory point of view. However, their effectiveness in promoting safer use of medicines by consumers may be limited.

Educational materials make up an additional type of communication tool. Not only do they provide patients and healthcare professionals with information on the risks of medicines, but they also encourage them to have **one-on-one** discussions on safety data .

This e-book chapter summarizes and reflects on forms of communication with citizens. It highlights the following aspects:

- Target – the public being addressed needs to be considered: healthcare professionals, general public or mass media;
- Comprehensibility – clarity and plainness;
- Honesty – risks should not be downplayed nor any uncertainty omitted;
- Informativeness – information should be included so that the reader will understand the message, will know what to do in case of concern and whom to address for additional clarification;
- Appropriateness – this is the final litmus test: Is it clear for the reader that both benefits and risks have been taken into consideration? Is the message being put across generally correct?

To read more online or download the E-book click here

Communications to Healthcare Professionals published on the Infomed product information webpage

Click on the links.

INN Medicinal product	Target	Comunication Online publication date
Mecasermin Increlex	**Physicians:** specialists in paediatric endocrinology and paediatricians who provide endocrinological care in hospitals **Pharmacists:** hospital pharmacy directors at organizations using *Increlex*	Risk of benign and malignant neoplasms 02-12-2019

Compiled by Patrícia Catalão