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New Infarmed ADR Portal (Portal RAM): FAQs

• What is Portal RAM and how can I access it?

Portal RAM is a fast track online platform for healthcare professionals and patients to report adverse drug reactions to the medicines authority Infarmed. It can be accessed through a link at the bottom of **Infarmed**'s website (Online Services section).

• Is Portal RAM easy to use?

Yes. All the compulsory fields can be very intuitively filled in in less than five minutes. In many cases help is available and flagged with an «**i**».

• Do I have any benefits from registering?

Yes. Should you register and log up to the **Infarmed website** all your personal data will be automatically filled out whenever you log back in after having reported an ADR at least once before. Moreover, you can leave off a report and come back to it later without losing any of the data you had already inserted. You can also search all the history of your previous reports.

• Which resources can I look up to help me to report an ADR?

- For any doubts about how to use Portal RAM: User Manual in the Portal's homepage.
- To find out whether an ADR is already listed (not unexpected): Summary of the Product's Characteristics at **INFOMED**.
- To find out the number of cases of a given ADR: **European database** or **World Health Organization international database**.

• Which is the minimum information I need to enter to report a case?

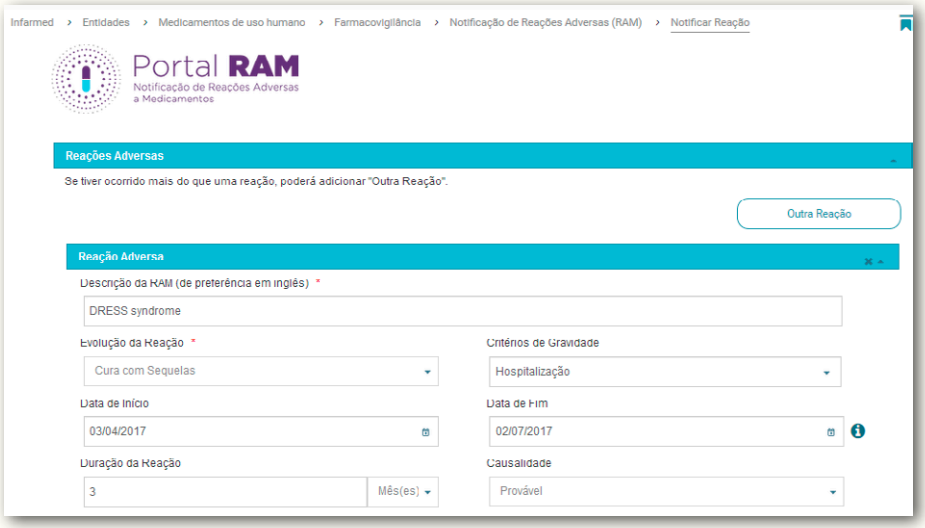
For the case to be validated you need only enter the adverse reaction, the medicinal product you suspect may have caused it, the patient who suffered it, and the person reporting it.

• How can I enter case data into Portal RAM?

You have 5 tabs that you need to fill out just like a regular form.

1. Adverse Reaction tab

In the ADR description box you can describe the adverse reaction using free text or a standard term in English which is automatically suggested once you have keyed in the term's first four letters (this is fed by MedDRA, the medical dictionary for regulatory matters).



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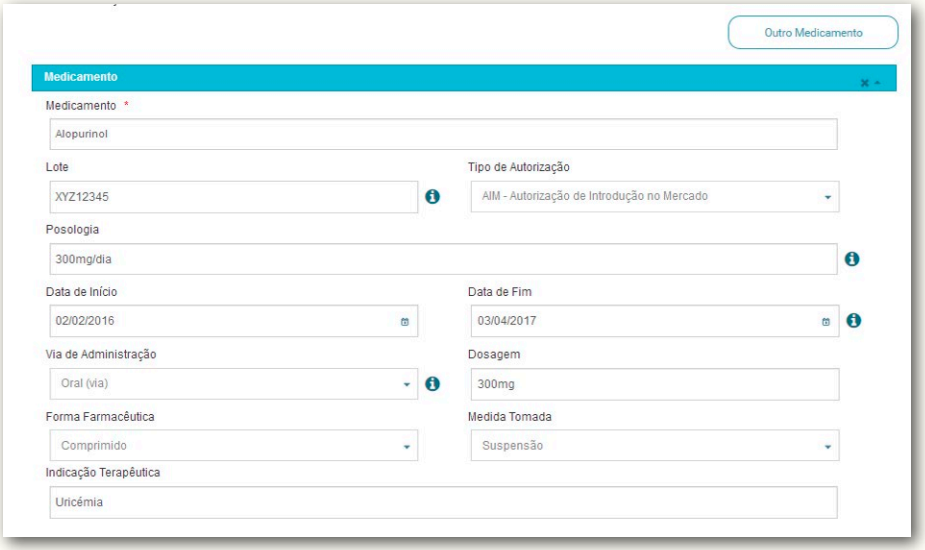
New Infarmed ADR Portal (Portal RAM): FAQs (cont'd)

2. Medicinal Product tab

Here only the suspected or interacting medicines should be mentioned. Concomitant medicines (which are not suspected to have caused the reaction) can be reported under the Other Information tab. The only compulsory field under this tab also gives you a choice between free or semiautomatic text and between trademark name (preferable) or INN. The batch number is compulsory in the case of biologicals and indispensable for the investigation of any suspected quality defect.



3. Patient tab

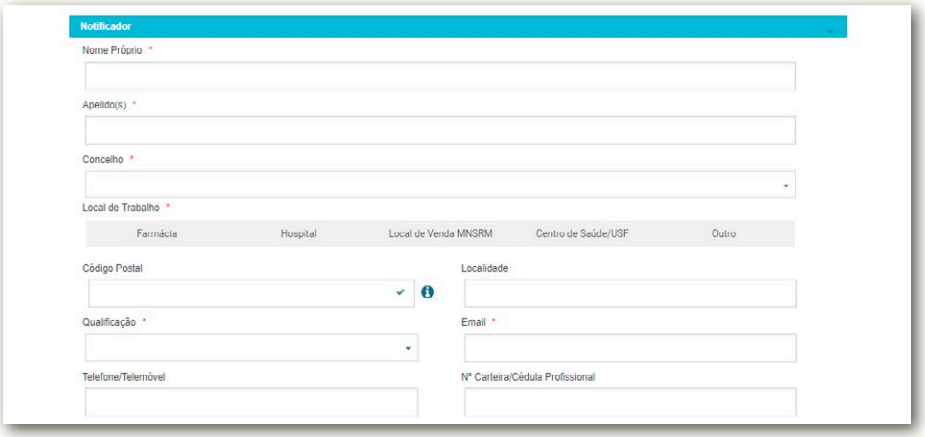
The patient should be anonymized by using initials instead of their name. Height and weight may be relevant in the case of injectable products whose dose is patient weight dependent.

4. Reporting Person tab

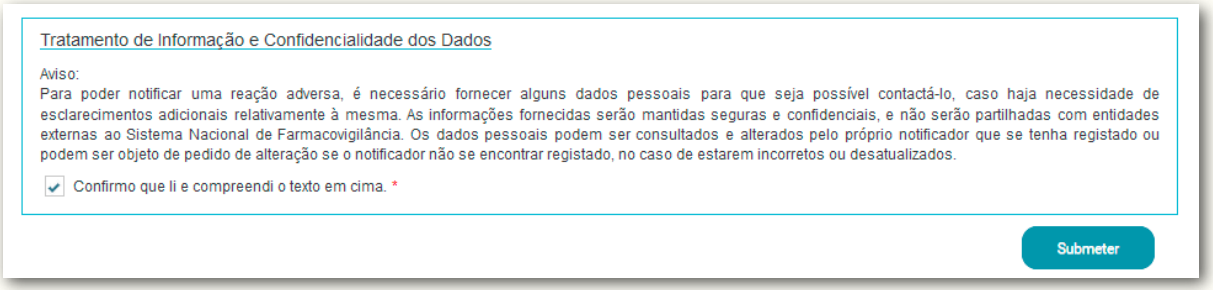
In this tab, in the case of healthcare professionals, the address data refer to the workplace.

5. Other Information tab

This is for any other data that will not fit in the fields above, e.g., known allergies, suspected interaction with other medicines or herbal products, etc.



- **How is the patient's and the reporting person's confidentiality protected?**
  The patient's data are anonymized and the reporting person's data can only be used strictly within the scope of the National Pharmacovigilance System.



- **Will I receive a confirmation after I have submitted an ADR case?**
  You will receive an automatic email from Portal RAM containing your case registry number and an attachment with a summary of the data you have entered. If Infarmed assesses the case as serious you will also receive an email with the result of the causality assessment and sometimes also other information regarding the case. **Please do not reply to those emails. To contact the National Pharmacovigilance System use farmacovigilancia@infarmed.pt**

Fátima Pereira de Bragança

Vancomycin
New recommendations for use

Quick Read
Within the scope of the fight against antimicrobial **resistance** and following a review of efficacy and safety data of all the products containing vancomycin, new recommendations have been adopted by the European Commission regarding the use of this antibiotic in the treatment of serious infections caused by Gram-positive bacteria (see shaded box below).

Vancomycin is a glycopeptide antibiotic authorized since the 1950s and which goes on being a relevant therapeutic option for the treatment of serious infections caused by Gram-positive bacteria. Its effect is essentially bactericidal through inhibition of the synthesis of the cell wall's peptidoglycan.
Vancomycin IV is mostly used for the treatment of serious infections caused by microorganisms endowed with resistance mechanisms against beta-lactam antibiotics, namely methicillin-resistant Staphylococcus aureus (MRSA), coagulase-negative Staphylococci (CoNS) and Enterococci. It is also used in patients who are allergic to penicillin and cephalosporins. Vancomycin is additionally given orally for the treatment of Clostridium difficile infection.

Increasing rates of bacterial resistance and tolerance to vancomycin combined with this antibiotic's pharmacodynamic (slow bactericidal activity, variable tissue penetration) and clinical limitations (therapeutic failure in patients with invasive infections by Staphylococcus aureus with a MIC higher than 1 mcg/ml) have brought this drug's current role into question. Following a request from the Spanish medicines agency (AEMPS), EMA undertook a benefit-risk assessment of vancomycin-containing medicinal products based on a review of all available data. It was concluded that the benefit-risk balance remains favourable provided use is in accordance with the following recommendations:

- → Vancomycin **solutions for infusion** can be used for the treatment of:
  - complicated soft tissue, bone and joint infections
  - community or hospital acquired pneumonia (including associated with the use of ventilators)
  - infective endocarditis (also for perioperative prophylaxis in at-risk patients)
  - acute bacterial meningitis
  - bacteraemia associated with the above infections.
- → The recommended **initial dose** should be based on the patient's age and weight (the previously recommended daily dose frequently resulted in suboptimal blood serum concentrations).
- → Any subsequent **dose adjustment** should always take into account the blood serum concentrations necessary for the target therapeutic concentrations to be reached.
- → The **parenteral formulations** of vancomycin authorized for oral administration can only be used for the treatment of Clostridium difficile infections, in patients of all ages.
- → The **parenteral formulations** of vancomycin authorized for intraperitoneal administration can be used for the treatment of peritoneal dialysis associated peritonitis, in patients of all ages.

In Portugal, medicinal products containing vancomycin are of exclusive hospital use and are available as powder for solution for injection or infusion (500 mg and 1000 mg). They can be given as injection, perfusion and orally, under certain conditions. The capsule formulation is not marketed in this country. The SmPC and PIL are being updated accordingly. To know more you can read the Infarmed **Information Circular** and the **assessment documents** available on EMA's website.

Magda Pedro

Communications to Healthcare Professionals published on the Infarmed website

Click on the links

INN Medicinal product	Target	Communication Online publication date
Fingolimod Gylenia	**Physicians:** neurology.	Contraindications in patients with cardiac conditions 20-11-2017
Tramadol Tramal, gotas orais, solução	**Pharmacists:** hospital and community. **Physicians:** general/family medicine, internal medicine, paediatrics, ENT, orthopaedics and oncology.	Clarification of dosage given by dose pump following cases of accidental overdose 22-11-2017

Compiled by Magda Pedro

Educational Materials published in the Infomed product information webpage

Click on the links

INN Medicinal product	Target	Communication Online publication date
Zoledronic acid Aclasta	**Patients**	Alert card on osteonecrosis of the mandible 24-11-2017

Compiled by Magda Pedro

What do they mean?

ADR	Adverse Drug Reaction
EMA	European Medicines Agency
MA	Marketing Authorization
PIL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee (EMA)
SmPC	Summary of Product Characteristics