DGI - 039

GUIDE TO THE PREPARATION AND ADMINISTRATION OF INJECTABLE CYTOTOXIC DRUGS

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BACKGROUND

The preparation of injectable cytotoxics is a key activity of many hospital pharmaceutical services. Due to the increasing availability of cytotoxic medicines, either branded or generic, the time spent by hospital pharmacists in search of information about reconstitution and/or dilution, conservation and stability of these drugs has increased. In order to effectively respond to this information need, it would be useful to have a database that gathers all that information for all cytotoxic medicines currently available in Portugal.

PURPOSE

Elaboration of a preparation and administration guide of all injectable cytotoxics available in Portugal, that provides information on the reconstitution and/or dilution, conservation and stability, routes of administration, infusion rate, apart from other relevant observations.

MATERIALS AND METHODS

Review of the summary of product characteristics (SPC) of all injectable cytotoxic drugs currently available in Portugal and consultation with the pharmaceutical laboratories and analysis of the received responses.

RESULTS

A total of 153 injectable cytotoxic medicines were analyzed (88 branded and 65 generic), comprising a total of 40 active substances. Of this total, 145 have a marketing authorization in Portugal and 8 are used under a special-use authorization. It was observed a significant variability in the information available about the reconstitution, dilution, conservation, administration and stability, when considering the different medicines of the same active substance, which depends on the pharmaceutical producer. In all, 32 laboratories were requested to add additional relevant information that was not present on the SPC. The guide is available in electronic format and in A5 print format (handbook), which has proved to be of very practical, fast and effective use.

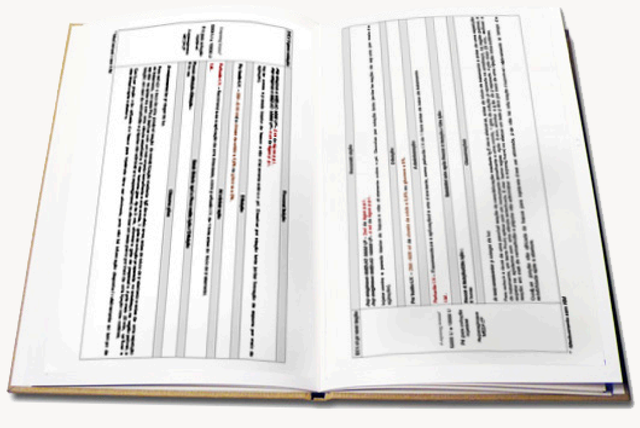

TABLE 1 – Table of reconstitution, dilution, administration, stability after reconstituion/dilution and observations of injectable cytotoxic drugs. (Example from guide).

Drug	Reconstitution
Dacarbazine 500 mg e 1000 mg Powder for solution for infusion Dacarbazine MEDAC®	50 ml of water for injection. **Dilution** 200 – 300 ml of sodium chloride infusion or glucose 5%. ***Dacarbazine MEDAC 500 mg®*** – The obtained infusion solution will have 1,4 – 2,0 mg/ml. ***Dacarbazine MEDAC 1000 mg®*** – The obtained infusion solution will have 2,8 – 4,0 mg/ml. **Administration** I.V. – Slow injection or infusion. **Infusion** – Administer over 15 – 30 min. **Stability after reconstitution / dilution** **Reconstitution / Dilution:** The reconstituted and further diluted solution must be used immediately; protect from light. **Observations** **Storage:** ≤ 25ºC; protect from light. Dacarbazine is sensitive to light exposure. During administration, the infusion container and administration set should be protected from exposure to daylight, e.g. by using light-resistant PVC-infusions sets. Chemically incompatible with heparin, hydrocortisone, L-cysteine and sodium hydrogen carbonate. The diluted solution for infusion should be visually inspected and only clear solutions practically free from particles should be used. Do not use the solution if particles are present. Any portion of the contents remaining after use should be discarded.

CONCLUSIONS

The published guide is a valuable tool for all Portuguese hospital pharmacists that prepare parenterally administered chemotherapy, answering to most information needs on reconstitution, dilution, conservation, stability and administration of injectable cytotoxic drugs.

CONFLICTS OF INTEREST: NOTHING TO DISCLOSE

18th Congress of eahp european association of hospital pharmacists
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"Improving patient outcomes – a shared responsibility"