Practice sting 2025-07

Practice sting Confusing Strength Labelling of Combination Products

This Practice Sting is particularly relevant for pharmaceutical manufacturers, guideline and reference manual authors, prescribers, pharmacists, and nurses.

Correctly calculating the dosage of combination products sometimes goes wrong, as illustrated by the report below.

Incident

A doctor prescribes an injection of 720 mg cotrimoxazole to a seriously ill child. The nurse prepares the injection using ampoules of cotrimoxazole with 80 mg sulfamethoxazole and 16 mg trimethoprim per millilitre. The nurse assumes that the 720 mg refers to sulfamethoxazole, as does the colleague who checks the calculation. The calculated amount is administered, resulting in the child receiving 720 mg of sulfamethoxazole and 144 mg of trimethoprim. The intended dosage was exceeded by 20%. The correct dosage instruction was available in the electronic administration records.

Analysis

If the nurses had carefully checked the administration record, the dosing error might have been prevented. However, correctly interpreting the dosage of a combination product like cotrimoxazole is not (always) straightforward.

Cotrimoxazole is a combination product consisting of trimethoprim and sulfamethoxazole in a 1 to 5 ratio. In the Netherlands, there is no uniform strength indication in the naming of the various products. Commonly used reference works and guidelines do not consistently present the dosage of cotrimoxazole. Some sources list the dosage as the sum of the components, while others specify the amount per individual component. This phenomenon also occurs in other combinations, for example levodopa/benserazide and diclofenac/misoprostol.

The combination products mentioned above were all registered around the 1980s. Since then, the policy on naming conventions has been revised, but the strength indication of these products has remained unchanged. According to the current policy of the Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen), adding together the strengths of the individual components in combination products is no longer permitted. In line with this, confusion regarding strength indication in newly registered combination products will no longer occur.

The variation in how strength and dosage are presented, as seen with cotrimoxazole, can lead to confusion and increases the risk of dosing errors. This is especially true for dosage forms such as liquids, suspensions, and injections, which must be measured before administration. Additionally, the information provided in ICT systems does not always optimally support healthcare professionals who prescribe, dispense, and administer these medicines. Some ICT systems list both the brand name — *Bactrimel infusion fluid concentrate ampoule 5 ml* — and the PRK name — *Cotrimoxazole 96 Infopl conc 16/80 mg/ml amp 5 ml*. Other systems only mention the brand name *Bactrimel infusion fluid*

concentrate ampoule 5 ml. In the latter case, nurses lack information about the ampoule's strength, which can lead to errors when preparing and administering an injection.

Recommendations

Applicable to all combination products

For Pharmaceutical Manufacturers

- Include the strengths of all active ingredients separately in the name of combination products.
- Update the names of older combination products in accordance with the current policy on the Naming of Pharmaceutical Products.

For Authors of Guidelines and Reference Works

Clearly state the strengths of all active ingredients separately for combination products.

Specifically Regarding the Incident in This Report

For Nurses

Before administering a medicine, carefully check the administration record and contact the prescriber or pharmacist if anything is unclear.

For Prescribers

Ensure it is clear what the cotrimoxazole dosage is based on: the total number of milligrams of sulfamethoxazole and trimethoprim combined, or the number of milligrams of each individual component.

For Pharmacists

Ensure that both the pharmacy label and the administration record clearly indicate what the cotrimoxazole dosage is based on: the total number of milligrams of sulfamethoxazole and trimethoprim combined, or the number of milligrams of each individual component.