



ORIGINAL ARTICLE

## Has the use of antipyretics been modified after the introduction of different concentrations of ibuprofen into the market?☆



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### KEYWORDS

Drug use;  
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Fever;  
Off-label use;  
Children

### Abstract

**Introduction:** Due to the emergence of new pharmaceutical presentations of ibuprofen (40 mg/mL), an analysis was made on the use of antipyretics in paediatric outpatients in Spain. **Patients and methods:** A cross-sectional, observational, descriptive study was carried out on a sample of children under 14 years old with treated febrile syndrome, seen in the Emergency Room of the Hospital General Universitario de Valencia from November 2012 to January 2013. **Results:** Of the 217 children included, 144 were treated with paracetamol or ibuprofen, 69 received both drugs, and one received paracetamol and metamizol. There were 58.7% of exposures to paracetamol and 40.9% to ibuprofen. The parents decided the use of antipyretics in 63.2% of cases. In 98 exposures the dose was different from that authorised in the labelling of the drug (off-label use). Ibuprofen was used off-label in 40.2% of cases, mostly by underdosing (35.9%). Paracetamol was used off-label in 29.8% of cases, predominantly overdose (26.8%), with the difference being statistically significant. No significant differences were observed in the off-label use in either monotherapy or combined use. There were also no differences when antipyretics prescribed by doctors or given directly by parents were evaluated separately. **Conclusions:** The majority of children with treated febrile syndrome seen in the Emergency Room were receiving antipyretic drugs after a parental decision. Paracetamol is the most commonly used drug and one in three children received it simultaneously with ibuprofen. The antipyretics were used off label in one-third of the cases. Off label use of ibuprofen is increasing, and is probably due to the existence of different pharmaceutical presentations.

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**PALABRAS CLAVE**

Utilización de medicamentos;  
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Fiebre;  
Uso «off-label»;  
Niños

## ¿Se ha modificado el uso de antitérmicos tras la introducción de ibuprofeno a diferentes concentraciones?

**Resumen**

**Introducción:** Se analiza la utilización de antitérmicos en pediatría extrahospitalaria en España después de la aparición de medicamentos con 40 mg/mL de ibuprofeno.

**Pacientes y métodos:** Estudio transversal, observacional y descriptivo en pacientes menores de 14 años con síndrome febril ya tratado, atendidos en Urgencias del Servicio de Pediatría del Consorcio Hospital General Universitario de Valencia entre noviembre del 2012 y enero del 2013.

**Resultados:** De 217 niños, 144 estaban tratados con paracetamol o ibuprofeno, 69 recibían ambos fármacos, y uno paracetamol y metamizol. Hubo un 58,7% de exposiciones a paracetamol y un 40,9% a ibuprofeno. En el 63,2% de los casos el uso de antitérmicos fue decidido por los padres. En 98 exposiciones la dosis fue diferente de la autorizada en la ficha técnica (uso «off-label»). El 40,2% de las exposiciones a ibuprofeno fue «off-label», en su mayoría por infradosificación (35,9%). Paracetamol se usó «off-label» en el 29,8% de los casos, predominando la sobredosificación (26,8%), diferencia estadísticamente significativa. No hubo diferencias significativas en el uso «off-label» combinado o en monoterapia.

**Conclusiones:** La mayoría de los niños con síndrome febril que llegan a urgencias con tratamiento antitérmico reciben este por decisión de sus padres. El paracetamol es el fármaco más usado, uno de cada 3 niños lo reciben simultáneamente con ibuprofeno. En un tercio de las ocasiones, los antitérmicos son utilizados al margen de la ficha técnica con una tendencia creciente que, en el caso del ibuprofeno, puede estar relacionada con la existencia de presentaciones farmacéuticas con distintas concentraciones.

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**Introduction**

Fever is a very frequent reason for paediatric visits. Although it is a physiological response of the body to various conditions, especially infection, it commonly generates anxiety and unwarranted fear in parents, a phenomenon that has been termed “fever phobia” that often leads to aggressive treatment of the fever.<sup>1,2</sup>

The drugs used most commonly to treat fever are paracetamol or ibuprofen, either alone or in alternation. The dosage forms used most frequently in paediatrics are ibuprofen oral suspensions and paracetamol solutions.<sup>1</sup>

Several studies<sup>1,3,4</sup> show that the combined or alternating use of both drugs is not justified, because while it is more efficacious in reducing the temperature in the first hours of treatment, it carries a higher risk of dosage errors, and thus of incorrect use and potential liver and kidney toxicity. On the other hand, early or aggressive treatment of fever does not reduce the risk of febrile seizures, to the point that a recent update of British guidelines recommended using antipyretic drugs only when there is discomfort, and not with the sole purpose of bringing the body temperature down to normal.<sup>5</sup>

In Spain, different liquid formulations are available for both paracetamol and ibuprofen.<sup>6-8</sup> Paracetamol is available in four different concentrations, but the one most commonly used is 100 mg/mL. There are 10 brands, of which 7 correspond to this concentration. There are 2 ibuprofen liquid formulations. The oldest one, with the lower concentration, is the 20 mg/mL formulation and it is either orange or white in

colour. There are 13 different brands for this dosage form. In 2003 a more concentrated dosage form, with 40 mg/mL, was introduced in the market, of which there are now 7 brands available. At first, the form with the lower concentration was used in younger children, and the one with the higher concentration in older children. In recent years, following the introduction in 2008 of a 40 mg/mL formulation by the leading brand in the market, both concentrations started to be used interchangeably. Until January 2012, all the ibuprofen 40 mg/mL formulations were pink or red, but at this time a new orange-coloured formulation was introduced. These circumstances can contribute to dosage errors.

The summary of product characteristics and the patient information leaflet of a drug, addressed to healthcare professionals and patients, respectively, contain the necessary information for the correct use of the medicine. In Spain, the use of drugs outside of what is authorised in the summary of product characteristics is referred to by the English term “off-label use,” as it is not covered by the information available in the label. There is no Spanish equivalent for this English expression, although perhaps the closest would be “uso al margen de la ficha técnica” (use outside of the summary of product characteristics). Neubert defined off-label use as the use of an approved drug in an unapproved way.<sup>9</sup> This type of use must not be confused with the use of drugs under special circumstances, regulated by the Real Decreto (Royal Decree [RD]) 1015/2009, which refers to usage hitherto known as “compassionate”.

A study on the use of medication in outpatient paediatric patients found that in 30% of a total of 148 children with

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