CLINICAL CASE OF AN ADVERSE DRUG REACTION DUE TO THE ADMINISTRATION OF AN ESTROGENE/GESTADENE COMBINATION DRUG

CPC-030

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Background:

Different European countries have different Summary of product characteristics (SmCP) for the same registered drug, this lead to an unequal level of safety information.

Purpose:

Description of an ADR in a child after administration of Fedra ® (gestodene + ethinylestradiol) not reported in the Italian SmCP case report.

Materials and Methods:

The Pediatric Emergency department of our hospital admitted a 15 years old girl with frequent hand, foot and facial paresthesias of the body's right side.
The patient was under treatment with Fedra ® from 10 days due to menstrual irregularity.

Results:

At the admission, the general status of the patient, monitored by blood, clotting test and imaging studies (CT and brain MRI) appeared in the normality levels. During the hospitalization estro-progestin therapy was suspended with gradual resolution of symptoms with negative neurological follow-up.
A report for these ADR has been submitted to the Agenzia Italiana del Farmaco (AIFA) and to the database of MEAP project (monitoring adverse drug reactions in pediatric patients).
Applying the Naranjo algorithm this ADR (frequent hand, foot and facial paresthesias of the body's right side) was classified as "possible".
However, if in the AIFA database there are 33 ADR related with the administration of the combo "gestodene + ethinylestradiole" related to the nervous system, including paresthesias (pic.1). These reactions are not mentioned in the Italian SmCP, when in the British SmCP they are classified as "well-known side effect" for the same combo, registered under the trade name of Triminulet ®.

Pic. 1

Conclusions

This case study suggest the importance of point out all the symptoms, even the minor ones not yet known, especially in the pediatric patients to better evaluate the safety profile of the drug in this particular population.

Diseases of the nervous system	Deaths	Serious	Not serious	Not indicated	Total	%
Coma	1	0	0	0	1	4,20%
Headache	0	0	0	1	1	4,20%
Paresthesia	0	2	0	0	2	8,30%
Pre-syncope	0	0	0	1	1	4,20%
Hemorrhagic stroke	0	1	0	0	1	4,20%
Cerebral Infarction	0	1	0	0	1	4,20%
Cerebral Ischemia	0	1	0	0	1	4,20%
Cerebral Thrombosys	1	0	0	0	1	4,20%
subarachnoid hemorrhage	0	1	0	0	1	4,20%

Pic.1: Data Processing AIFA