ASSESSMENT OF THE USE OF THE VEMONIS FEMI® MEDICINAL PRODUCT IN THE TREATMENT OF DYSMENORRHEA IN EVERYDAY CLINICAL PRACTICE (ADM/VEM/2020)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35006

EU PAS number

EUPAS35005

Study ID

35006

DARWIN EU® study

No

Study countries

☐ Poland

Study description

The composite preparation containing sodium metamizole, caffeine and drotaverine hydrochloride VEMONIS FEMI® is used for the symptomatic treatment of pain, pain associated with smooth muscle spasms (renal colic, dysmenorrhea, intestinal colic, irritable bowel syndrome, cholecystitis, cholangitis) when the use of other drugs is contraindicated or ineffective. Metamizole is a pyrazolone derivative, belongs to NSAIDs with analgesic, spasmolytic and antipyretic effects. The analgesic effect of this substance is based on inhibition of COX3 occurring mainly in the CNS, which results in decreased synthesis of PGE2, which reduces the sensitivity of nociceptors to pain mediators. Metamizole metabolites are CB1, which are part of the descending antinociceptive system. The third mechanism associated with the analgesic properties is the activation of the endogenous opioid system. Metamizole differs from other NSAIDs as it has a clear spasmolytic effect. The mechanism responsible for this effect may be the inhibition of intracellular release of calcium ions, which causes smooth muscle relaxation. Furthermore, it inhibits the accumulation of inositol phosphate by direct inhibition of phospholipase C or by impairing the activation of the receptor that is combined with protein G. Caffeine is a naturally occurring methylxanthine used as a CNS stimulant. Its other effects: relaxation of smooth muscles, stimulation of the heart muscle and stimulation of diuresis. It’s also effective in treating certain types of headaches. Caffeine inhibits phosphodiesterase, an enzyme inactivating the cyclic adenosine monophosphate. It shows antagonistic effects against adenosine receptors A(1), A(2A), A(2B) involved in nociception. It is an additive to many painkillers because it increases their analgesic effect by accelerating their absorption. Drotaverine is a relaxant, structurally similar to papaverine but with a much stronger effect. It is a selective inhibitor of PDE4 in

smooth muscles.

Study status

Ongoing

Research institutions and networks

Institutions

Europharma

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Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Planned: 05/02/2020

Actual: 05/02/2020

Study start date
Planned: 15/04/2020

Actual: 15/04/2020

Data analysis start date
Planned: 30/07/2020

Date of final study report
Planned: 30/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Adamed Pharma S.A.

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

Main aim of the Study: Assessment of the use of VEMONIS FEMI® in the treatment of dysmenorrhea in everyday clinical practice in the population of Polish women using this preparation. Additional aim of the Study: The assessment of the treatment efficacy and tolerance.

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

350

Study design details

Outcomes

Assessment of the use of VEMONIS FEMI® in the treatment of dysmenorrhea in everyday clinical practice in the population of Polish women using this preparation, The assessment of the treatment efficacy and tolerance.

Data analysis plan

20 gynaecologists and doctors currently in the process of obtaining the gynaecology specialization as well as 15 general practitioners, who utilize the VEMONIS FEMI® medicinal product the treatment of dysmenorrhea in their everyday clinical practice, will participate in the Study. Data on the use of VEMONIS FEMI® as well as the characteristics of the Patients in whom it was used as well as its tolerance and efficacy will be noted in the Study Questionnaires (SQ) during 3 consecutive, routine visits in three consecutive menstrual cycles.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No