Important notice

December 2023

Safety-related information for the product MIFEGYNE® 200mg (Pharmacode 2822574) and MIFEGYNE® 600mg (Pharmacode 6662274), active substance: Mifepristone

Dear Healthcare professional,

Nordic Pharma GmbH in agreement with Swissmedic would like to inform you of the following:

Summary:

- **The current MIFEGYNE® 200mg and MIFEGYNE® 600mg packages on the Swiss market do not contain a recently approved Patient Information Leaflet.** As a consequence a new adverse event: Acute Generalized exanthematous pustulosis (AGEP) under section "Possible side effects'' of the leaflet is missing. Furthermore a warning about serious skin side effect under section '' What you need to know before intake Mifegyne®?'' of the leaflet is missing.

- **MIFEGYNE® products with the following batch numbers are affected:**
  MIFEGYNE® 200mg: Batches 253, 253A, 262, 264
  MIFEGYNE® 600mg: Batches M246, M250, M260, M260A

Background information on this finding:

Acute Generalized exanthematous pustulosis (AGEP)

Two (2) cases of acute generalized exanthematous pustulosis (AGEP) have been reported in literature with close temporal relationship with mifepristone intake. No cases of AGEP with mifepristone has been found in the Nordic Pharma's Global safety database over the past 34 years since market launch. . AGEP is a rare, acute, severe cutaneous adverse reaction attributed mainly to drugs, although other triggers, including infections, vaccinations, ingestion of various substances, and spider bites, have also been described. It is characterized by the development of edematous erythema, usually in large skin folds, followed by the eruption of multiple punctate, non-follicular, sterile pustules and subsequent typical desquamation. The mainstay of treatment for AGEP is withdrawal of the offending drug. In cases caused by infection or other triggers rather than a drug, treatment of the underlying cause is an important part of management. The reaction usually resolves within 15 days, and the overall prognosis is good *(Parisi et al. Am J Clin Dermatol. 2023 Jul;24(4):557-575)*.

Change in SmPC and package leaflet

Taking into consideration the available published literature, the European Health Authority requested to the marketing authorization holders the implementation of new information in section ''Warnings and precautionary measures'' and ''Adverse effects'' of the SmPC. The Swissmedic had adopted the decision on the inclusion of a warning in section ''Warnings and precautionary measures'' of the SmPC, the addition of AGEP in section ''Adverse effects'' and an update of sections "Possible side effects'' and '' What you need to know before intake Mifegyne®?'' of the package leaflet.

Nordic Pharma GmbH
Binzmühlestrasse 80, CH-8050 Zürich
info.ch@nordicpharma.com Tel: +41 43 444 92 91

MIFEGYNE® products, currently available in the market, with the following batch numbers are affected:
MIFEGYNE® 200mg: Batches 253, 253A, 262, 264
MIFEGYNE® 600mg: Batches M246, M250, M260, M260A

The most recent package leaflet and SmPC can be found here: www.swissmedicinfo.ch

Call for reporting of adverse events:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.
For reports of adverse drug reactions (ADRs), Swissmedic recommends using the Electronic Vigilance System (ElViS) reporting portal developed for this purpose. All the necessary information can be found at www.swissmedic.ch.

Company contact point:
For further information, please contact Nordic Pharma GmbH:

Phone: +41 43 444 92 91
Email: info.ch@nordicpharma.com
Fax: +41 43 444 92 89
Website: www.nordicpharma.ch

Cécile Kaiser
Pharmacovigilanz-verantwortliche Person
Nordic Pharma GmbH

Dr. Christoph Wasem
Fachtechnisch verantwortliche Person
Nordic Pharma GmbH