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Review of oral methadone medicines containing povidone started

The European Medicines Agency has started a review of oral (by mouth) methadone medicines that also contain povidone. Methadone-containing medicines are used in rehabilitation programs in patients dependent on opioids, such as heroin, to prevent or reduce withdrawal symptoms in order to decrease the chance of relapse.

The review was triggered by the Norwegian Medicines Agency, NOMA, following a number of reports of kidney failure in former or current drug abusers which may be linked to the misuse of methadone oral solutions containing certain types of povidone. These medicines are intended for oral use only; however, some patients may abuse oral methadone preparations and inject them into a vein. If a medicine containing these forms of povidone is abused in this way, there are concerns that povidone can accumulate inside the cells of vital organs. This is not considered to occur when oral methadone medicines are used as recommended.

As a result of these concerns, on 8 April Norway suspended the only methadone-containing oral solution that contains povidone present on the national market, and has now asked the Agency to review whether there are implications for the use of all oral methadone medicines containing povidone in other European Union (EU) Member States.

The Agency will therefore review this safety concern and its impact on the benefit-risk balance of oral methadone medicines that contain povidone, and will issue an opinion on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

The Agency invites all stakeholders (e.g. healthcare professionals, patients' organisations, the general public) to submit data relevant to this procedure. Full details are available under the 'data submission' tab.

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More about the medicine

Methadone-containing medicines are used to treat drug addiction in patients dependent on opioids (such as heroin); methadone prevents or reduces opiate withdrawal symptoms, decreasing the chance of relapse. Methadone is also used in the treatment of severe pain.

Oral methadone medicines are available as solutions or tablets. Some of them also contain povidone, which is used in oral solutions as a suspending and dispersing agent, or as binding agent for tablets. Various forms of povidone are available, which vary in the size of the molecule. The forms that have been linked to the reported kidney problems have a large molecular size.

Oral methadone medicines containing povidone have been authorised via national procedures in the following countries: Bulgaria, Denmark, Finland, Hungary, Iceland, Luxembourg, Malta, Norway, Romania, Slovakia, Spain, Sweden and the United Kingdom.

More about the procedure

The review of methadone-containing medicines for oral use containing povidone has been initiated at the request of Norway, under Article 107i of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As methadone-containing medicines containing povidone are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh, a body representing EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.