

**Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a)
zákona č. 378/2007 Sb., o léčivech a o změnách
některých souvisejících zákonů (zákon o léčivech), ve
znění pozdějších předpisů (1)**

Oxytocin AVMC 5 IU/ml injekční/infuzní roztok

Administrativní informace:

Léčivá látka/látky	oxytocin
Léková forma/formy	injekční/infuzní roztok
Síla/síly	5 IU/ml
Držitel rozhodnutí o registraci	AV Medical CZ s.r.o.
Registrační číslo/čísla	56/227/23-C
Verze a datum plánu řízení rizik	Verze: 3.0 Datum: 20/08/2025

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) [Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů](#)

Summary of risk management plan for Oxytocin AVMC (oxytocin)

This is a summary of the risk management plan (RMP) for Oxytocin AVMC. The RMP details important risks of Oxytocin AVMC, how these risks can be minimised, and how more information will be obtained about Oxytocin AVMC's risks and uncertainties (missing information).

Oxytocin AVMC's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Oxytocin AVMC should be used.

Important new concerns or changes to the current ones will be included in updates of Oxytocin AVMC's RMP.

I. The medicine and what it is used for

Oxytocin AVMC is authorised for:

Antepartum

Induction of labour for medical reasons,

Stimulation of labour in hypotonic uterine inertia,

In early stages of pregnancy as an adjunctive therapy for the management of incomplete, inevitable, or missed abortion.

Postpartum

During caesarean section but following delivery of the child and for prevention and treatment of postpartum uterine atony and haemorrhage.

(see SmPC for the full indication).

It contains Oxytocin as the active substance, and it is given by intravenous infusion and intramuscular injection.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Oxytocin AVMC, together with measures to minimise such risks and the proposed studies for learning more about Oxytocin AVMC's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Oxytocin AVMC are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Oxytocin AVMC. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

In order to harmonise risks the safety information in the proposed Product Information is aligned to the product Oxytocin Orifarm (ORIFARM GROUP A/S) published on the CMDh website from Rev.35 from 09/2022 II.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Oxytocin AVMC.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Oxytocin AVMC.