# Summary of risk management plan for DABIGATRAN ETEXILATE ORION 75 MG, 110 MG AND 150 MG CAPSULES (DABIGATRAN ETEXILATE) Orion Corporation

# DATE: 19-01-2026, VERSION 2

---

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

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

Important new concerns or changes to the current ones will be included in updates of Dabigatran etexilate Orion's RMP.

## I. The medicine and what it is used for

Dabigatran etexilate Orion is used:

In adults to:

-prevent the formation of blood clots in the veins after knee or hip replacement surgery

-prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor

-treat blood clots in the veins of your legs and lungs and to prevent blood clots from re-occurring in the vein of your legs and lungs.

In children to:

-treat blood clots and to prevent blood clots from reoccurring (see SmPCs for the full indications).

It contains dabigatran etexilate as the active substance and it is given by mouth.

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

Important risks of Dabigatran etexilate Orion, together with measures to minimise such risks and the proposed studies for learning more about Dabigatran etexilate Orion'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.

In the case of Dabigatran etexilate Orion, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

## II.A List of important risks and missing information

In the case of Dabigatran etexilate Orion, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | Haemorrhage |
| Important potential risks | None |

| List of important risks and missing information | |
|---|---|
| Missing information | Paediatric patients with renal dysfunction (eGFR <50ml/min) |

## II.B Summary of important risks

| Important identified risk: Haemorrhage | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br><br>SmPC sections 4.2, 4.3, 4.4, 4.5, 4.8 and 4.9.<br><br>PL sections 2, 3 and 4.<br><br>Prescription only medicine.<br><br>Additional risk minimisation measures:<br><br>Educational pack |

| Missing information: Paediatric patients with renal dysfunction (eGFR <50ml/min) | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br><br>SmPC sections 4.2 and 4.4.<br><br>PL section 2.<br><br>Prescription only medicine.<br><br>Additional risk minimisation measures:<br><br>None |

## II.C Post-authorisation development plan

There are no studies required for Dabigatran etexilate Orion