

Summary Public Assessment Report

Carboprost Alembic (carboprost trometamol)

SE/H/2389/01/DC

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Carboprost Alembic
carboprost trometamol

solution for injection, 0.25 mg/ml

This is a summary of the public assessment report (PAR) for Carboprost Alembic. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Carboprost Alembic and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Prostinfenem.

Carboprost Alembic is used to induce abortion and to treat bleeding that occurs within 24 hours of delivery.

How does Carboprost Alembic work?

Carboprost Alembic contains the active substance carboprost and belongs to a group of medicines called prostaglandins.

How is Carboprost Alembic used?

The pharmaceutical form is *solution for injection* for intramuscular administration.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Carboprost Alembic have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by intramuscular injection and contains the same active substance as the reference medicine, Prostinfenem.

What are the possible side effects from Carboprost Alembic?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Carboprost Alembic approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish

Medical Products Agency decided that, as for Prostifenem, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Carboprost Alembic?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Carboprost Alembic

The full PAR for Carboprost Alembic can be found on the following website: [MRI - Home](#). For more information about treatment with Carboprost Alembic, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09.