

PART III: CONSUMER INFORMATION**HEMABATE STERILE SOLUTION
(carboprost tromethamine injection USP)**

This leaflet is part III of a three-part "Product Monograph" published when HEMABATE STERILE SOLUTION was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HEMABATE STERILE SOLUTION. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

HEMABATE STERILE SOLUTION is used to stop excessive bleeding in women who have just given birth, when bleeding is due to the uterus (womb) failing to return to its normal size, and who have not responded to conventional treatments.

What it does:

HEMABATE STERILE SOLUTION belongs to a group of medicines called prostaglandins that acts to increase the contractions of the uterus (womb). This helps to control bleeding after delivery.

When it should not be used:

You should not be given HEMABATE STERILE SOLUTION if you:

- are allergic to carboprost tromethamine or any of the other ingredients of HEMABATE STERILE SOLUTION, in particular benzyl alcohol.
- have a heart, lung, kidney or liver disease.
- have an infection of your uterus, ovaries or fallopian tubes.

What the medicinal ingredient is:

carboprost

What the nonmedicinal ingredients are:

Benzyl alcohol, sodium chloride, tromethamine, and water for injections. Small amounts of hydrochloric acid and sodium hydroxide (used to regulate the acidity or alkalinity of the solution) may also be present.

What dosage forms it comes in:

HEMABATE STERILE SOLUTION is available as a sterile solution contained in an ampoule. Each ml contains 250 micrograms of carboprost.

WARNINGS AND PRECAUTIONS

HEMABATE STERILE SOLUTION must be given only by a health care professional experienced in the use of the drug in hospitals or clinics with specialized units for pregnancy and childbirth.

HEMABATE STERILE SOLUTION may cause temporary high fever, and rarely, heart and blood circulation failure or airway constriction.

BEFORE you are given HEMABATE STERILE SOLUTION, talk to your doctor or pharmacist if you currently have, or have had in the past any of the following conditions:

- lung disease, including asthma
- high or low blood pressure (including high blood pressure in pregnancy)
- heart disease or anaemia (low blood count)
- kidney or liver disease (including jaundice)
- glaucoma (raised pressure in your eyes)
- diabetes or epilepsy
- a caesarean section or any other operation on your womb

HEMABATE STERILE SOLUTION is not indicated for use in children. HEMABATE STERILE SOLUTION contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

Pregnancy

HEMABATE STERILE SOLUTION will only be given shortly after you have delivered your baby and not while you are still pregnant as it could put the embryo or foetus at risk.

Breast-feeding

It is not known if HEMABATE STERILE SOLUTION is excreted in human breast milk. However, breast-feeding is not recommended at least 6 hours after receiving the last dose of HEMABATE STERILE SOLUTION.

Driving and using machines:

Do not drive, use any tools or operate machinery soon after receiving HEMABATE STERILE SOLUTION as it may affect your ability to do so safely.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking, have recently taken or might take any other medicines, including any that you have bought without a prescription.

Tell your doctor if you are taking or have received oxytocin or ergometrine (ergonovine).

PROPER USE OF THIS MEDICATION**Usual dose:**

HEMABATE STERILE SOLUTION must be given to you as an injection deep into a muscle (intra-muscular). It must never be given by injection into a vein.

The first dose is usually 1 ml of solution (250 micrograms of carboprost). If needed the dose of 1 ml may be repeated between 15 to 90 minutes.

You should not be given more than 8 doses (8 x 250 micrograms of carboprost) altogether.

Overdose:

If you think you are given more HEMABATE STERILE SOLUTION than you should be, talk to your doctor or health care provider immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, HEMABATE STERILE SOLUTION can cause some side effects.

The following side effects are listed by frequency.

Very common (may affect more than 1 in 10 patients): diarrhoea, increased body temperature, pain behind the sternum that usually occurs on swallowing, nausea and vomiting.

Common (may affect up to 1 in 10 patients): cough, chills and shivering, inflammation of the uterus, flushing and hot flushes, headache, bleeding from the uterus, retained placenta or membranes.

Uncommon (may affect up to 1 in 100 patients): abdominal pain, pelvic pain, back pain, blurred vision, distortion of the sense of taste, dizziness, dry mouth, eye pain, fainting, hiccups, increased heart rate (tachycardia), increased blood pressure (hypertension), injection site pain, involuntary muscle contractions, muscle pain, ringing in the ears, shortness of breath, skin rash at injection site, sleep disorder, somnolence, stomach pain, sweating, tightness in chest and chest pain, torticollis, urinary tract infection, vertigo.

Unknown Allergic reactions such as: redness, itching or swelling of skin, hives, burning, stinging,

Other side effects may include:

- Anxiety and nervousness
- Breast tenderness
- Dry throat
- Excessive thirst
- Leg cramps
- Loss of strength and energy
- Nosebleed
- Palpitations
- Rash
- Retching
- Temporary loss of consciousness caused by a fall in blood pressure
- Twitching eyelids
- Upper respiratory tract infection

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Breathing difficulties, asthma, wheezing, hyperventilation		√	
	Septic shock		√	
	Uterine rupture, perforation of uterus		√	
	Vomiting of blood		√	
Unknown	Anaphylactic shock/reactions: swelling of the neck area, throat tightness, choking sensation or any difficulty with breathing, not present before using this medicine.		√	

This is not a complete list of side effects. For any unexpected effects while taking HEMABATE STERILE SOLUTION, contact your doctor or pharmacist.

HOW TO STORE IT

Ampoules must be stored in a refrigerator between 2 – 8°C. Your pharmacist will check the ampoules are still clear and colourless before use.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc. at: 1-800-463-6001

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