Package leaflet: Information for the user

Ofost 5 IU/ml concentrate for solution for infusion or solution for intramuscular injection
Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection
oxytocin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects serious, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ofost is and what it is used for

Each Ofost ampoule contains oxytocin 8.3 micrograms (equivalent to 5 IU) or 16.7 micrograms (equivalent to 10 IU) in 1 ml solution. Oxytocin is a hormone that contracts the smooth muscles in the womb.

Ofost is used:
- to start or help contractions during childbirth (labour);
- during caesarean section;
- to prevent and control bleeding after delivery of your baby;
- to help in the management of a miscarriage.

2. What you need to know before you receive Ofost

You must not receive Ofost
- if you are allergic to oxytocin or any of the other ingredients of this medicine (listed in section 6);
- if your doctor thinks that to start or increase contractions of the womb would be unsuitable for you, for example:
  - where there are obstructions that may prevent delivery;
  - where contractions of the womb are unusually strong;
  - where your baby may be short of oxygen.
- Where labour or vaginal delivery is not advisable, for example:
  - if your baby's head is too large to fit through your pelvis;
  - if your baby is wrongly positioned in the birth canal;
  - if the placenta lies near or over the neck of your womb;
  - if your baby lacks oxygen due to blood vessels running across the neck of your womb;
  - if the placenta separates from the womb before the baby is born;
  - if there are one or more loops of umbilical cord between the baby and the neck of the womb, either before or after your waters break;
  - if your womb is over-extended and more likely to tear, for example if you are carrying more than one baby or have too much water (amniotic fluid) in your womb;
  - if you have had five or more pregnancies in the past or if your womb is scarred by previous caesarean section or other surgery.

- If you have been given medicines called prostaglandins (used to bring on labour or treat stomach ulcers). Ofost should not be used for 6 hours after vaginal prostaglandins as the effects of both medicines may be increased.

Ofost should not be used for prolonged periods if:
- your contractions do not increase with the treatment;
- you have a condition known as severe pre-eclamptic toxaemia (high blood pressure, protein in the urine and swelling);
- you have severe problems with your heart or blood circulation.

If any of the above applies to you, or if you are not sure, talk to your doctor before you receive Ofost.

Warnings and precautions
Ofost should only be administered by a healthcare professional in a hospital setting.

Talk to your doctor or nurse before you receive Ofost if:
- you have had a previous caesarean section;
- you are prone to chest pain due to pre-existing heart and/or circulation problems;
- you have a known irregular heart beat ('long QT syndrome') or related symptoms, or are taking medicines known to cause the syndrome (see section *Other medicines and Ofost*);
- you have raised blood pressure or heart problems;
- you are more than 35 years old;
- you have kidney problems, as Ofost can cause water retention;
- you have had complications during your pregnancy (such as diabetes, high blood pressure, lack of thyroid hormone);
- you are more than 40 weeks pregnant.

When Ofost is given to start or help contraction during labour, the infusion rate should be set to maintain a contraction pattern similar to normal labour and adjusted to individual response. Too high doses may cause very strong continuous contractions and possibly tearing of the womb, with serious complications for you and your baby.

Ofost should not be given as rapid injection into a vein as this may cause decreased blood pressure, a sudden brief sensation of heat (often over the entire body), and an increased heart rate.

Ofost may rarely cause disseminated intravascular coagulation which causes symptoms including abnormal blood clotting, bleeding and anaemia.

High doses of Ofost may force amniotic fluid from your womb into your blood. This is known as amniotic fluid embolism.

High doses over a long period of time, whilst drinking or receiving large volumes of fluid may make your stomach feel very full, cause difficulty in breathing and lower salt levels in your blood.

Ofost must not be given simultaneously with oxytocin-containing nasal spray.

If any of the above applies to you, or if you are not sure, speak to your doctor or nurse before you receive Ofost.

Latex allergy
The active substance in Ofost might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy. Please tell your doctor if you know you are allergic to latex.

Children and adolescents
Ofost is not intended for use in children or adolescents.

Other medicines and Ofost
Tell your doctor if you are using, have recently used or might use any other medicines.
The following medicines may interfere with Ofost:
- prostaglandins (used to start labour or to treat stomach ulcers) and similar medicines as the effects of both medicines may be increased;
- anaesthetics (used to put you to sleep during surgery), e.g., cyclopropane or halothane, as their use with Ofost may cause problems with your heartbeat;
- medicines known to cause heart rhythm disturbances called 'long QT syndrome';
- epidural anaesthetics (used for pain relief during labour). Ofost may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

Ofost with food and drink
You may be told to keep the amount of fluids you drink to a minimum.

Pregnancy and breast-feeding
Ofost can start labour – it should only be used in pregnancy under medical supervision.
Ofost may be found in small amounts in breast milk but is not expected to have harmful effects because it is quickly inactivated by your baby's digestive system.
Ofost will not harm your newborn baby when breast-feeding.

Driving and using machines
Ofost can induce labour, therefore caution should be exercised when driving or operating machines.

3. How to use Ofost

Your doctor will decide when and how to treat you with Ofost. If you think that the effect of Ofost is too strong or too weak, tell your doctor. While you are receiving Ofost, both you and your baby will be closely monitored.

Ofost is usually diluted before use and given as an intravenous infusion (drip) into one of your veins. To prepare intravenous infusion your doctor may use Ofost 5 IU solution for injection/infusion.
Under certain circumstances, 1 ml of Ofost can be injected undiluted into a muscle.

The usual dose is different in the following circumstances:

To start or help contractions during labour
Ofost will be administered as drip infusion into your vein or, preferably, by means of a variable-speed infusion pump. For drip infusion it is recommended that 5 IU of Ofost be added to 500 ml of a physiological electrolyte solution (such as sodium chloride 0.9%). For patients in whom infusion of sodium chloride must be avoided, 5% dextrose solution may be used as the diluent.
The rate of infusion will start at 2-8 drops per minute (1 to 4 milliunits per minute). This may be gradually increased to a maximum rate of 40 drops per minute (20 milliunits per minute). The infusion rate can often be reduced once the contractions reach an adequate level, about 3-4 contractions every 10 minutes.
If your contractions do not reach the adequate level after 1 ml Ofost 5 IU/ml, the attempt to start labour should be stopped and then repeated the following day.

Caesarean section
The dose is Ofost 5 IU given as drip infusion (5 IU diluted in physiological sodium chloride solution) or preferably by means of a variable-speed infusion pump over 5 minutes into your vein after delivery of your baby.

Prevention of bleeding after delivery
The usual dose is 5 IU by infusion into your vein (5 IU diluted in physiological electrolyte solution) or 5-10 IU into a muscle after delivery of the placenta.

Treatment of bleeding after delivery
The dose is 5 IU of Ofost by infusion into a vein (5 IU diluted in physiological electrolyte solution) or 5-10 IU into a muscle. In some cases this may be followed by an i.v. drip containing 5 to 20 IU of oxytocin in 500 ml of a physiological electrolyte solution.

Miscarriage/Abortion
Due to lower receptor expression, the use of oxytocin is recommended from 14th week of pregnancy. The dose is 5 IU or 1 ml of Ofost 5 IU/ml given as drip infusion (1.0 ml diluted in physiological sodium chloride solution) or preferably by means of a variable-speed infusion pump over 5 minutes into your vein, if necessary followed by i.v. infusion at a rate of 20 to 40 milliunits/minute.

Patients with liver or kidney impairment
There is no information on use in patients with kidney or liver impairment.

Older people
There are no indications for use of Ofost in elderly patients.

If you receive more Ofost than you should
As this medicine is given to you in hospital, it is very unlikely that you will receive an overdose. If anyone accidentally receives this medicine, tell the hospital accident and emergency department or a doctor immediately. Show any left medicines or the empty packet to the doctor.
An overdose of Ofost could cause:
- harm to your baby;
- very strong contractions of your womb;
- damage to your womb which could include tearing;
- water retention, blood vessels spasm, high blood pressure.

If you miss a dose of Ofost
As a doctor is giving you this medicine, you are unlikely to miss a dose. If you have any worries, talk to your doctor.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

If the treatment with Ofost is stopped
Once labour is progressing, Ofost infusion may be gradually withdrawn.
There is no information regarding undesirable effects.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Ofost and contact a doctor or go to your nearest emergency department **immediately** if you experience any of the following symptoms:
- a severe allergic (anaphylactic/anaphylactoid) reaction with difficulty in breathing, dizziness and lightheadedness, feeling faint, nausea, cold and clammy skin or a fast or weak pulse. Rare – may effect up to 1 in 1,000 people
- swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema). Rare – may affect up to 1 in 1,000 people

Other side effects that may occur:

Common (may affect up to 1 in 10 people):
- headache;

- fast heartbeat;
- slow heartbeat;
- nausea;
- vomiting.

Uncommon (may affect up to 1 in 100 people):
- an irregular heartbeat.

Rare (may affect up to 1 in 1,000 people):
- skin rashes, hives.

Not known (frequency cannot be estimated from the available data):
- haemorrhage (bleeding);
- hypotension;
- chest pain (angina);
- irregular heartbeat;
- excessive or continuous contractions;
- tearing of the womb;
- fluid retention (water intoxication). Symptoms may include headache, anorexia (loss of appetite), feeling or being sick, stomach pain, sluggishness, drowsiness, unconsciousness, low levels of certain chemicals in the blood (e.g. sodium or potassium), fits;
- low blood salt levels;
- sudden fluid overload in the lungs;
- a rapid intravenous oxytocin injection can cause sudden short-term drop in blood pressure, sudden brief sensation of heat often over the whole body;
- abnormal clotting, bleeding and anaemia;
- spasm of the muscles of the womb.

Effects in the baby:
Excessive contractions may cause low blood salt levels, shortage of oxygen, suffocation and death.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ofost

Store in a refrigerator (2 ºC – 8 ºC). Do not freeze.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after EXP. The expiry date refers to the last day of that month.

After first opening: the medical product should be used immediately.
After dilution for infusion: from a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C.

Do not use any pack that is damaged or shows signs of tampering.
Do not use this medicine if you noticed the ampoule contents are cloudy or there are particles or flakes in it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ofost contains

- The active substance is oxytocin.

1 ml of solution contains 8.3 microgram oxytocin (5 IU).
1 ml of solution contains 16.7 microgram oxytocin (10 IU).
The other ingredients are sodium acetate trihydrate, acetic acid glacial, sodium chloride, sodium hydroxide (for pH adjustment), water for injection.

What Ofost looks like and contents of the pack

Colourless, clear liquid, free from visible particles.
pH of solutions 3.5-4.5

1 ml transparent type I borosilicate glass ampoules with break ring or open point cut.
Pack sizes: 5, 10 or 100 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

AS Grindeks, Krustpils iela 53, Rīga, LV-1057, Latvia

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden	Oxytocin Grindeks 8,3 mikrogram/ml injektions-/infusionsvätska, lösning
	Oxytocin Grindeks 16,7 mikrogram/ml injektions-/infusionsvätska, lösning
Austria	Oxytocin Grindeks 5 I.E./ml Injektions-/Infusionslösung
	Oxytocin Grindeks 10 I.E./ml Injektions-/Infusionslösung
Belgium	Oxytocin Grindeks 5 U.I./1 mL, solution injectable/pour perfusion
	Oxytocin Grindeks 10 U.I./1 mL, solution injectable/pour perfusion
	Oxytocin Grindeks 5 IU/ml Injektions-/Infusionslösung
	Oxytocin Grindeks 10 IU/ml Injektions-/Infusionslösung
	Oxytocin Grindeks 5 IU/ml oplossing voor injectie/infusie
	Oxytocin Grindeks 10 IU/ml oplossing voor injectie/infusie
Czech Republic	Ofost 5 IU/ml injekční/infuzní roztok
	Ofost 10 IU/ml injekční/infuzní roztok
France	OXYTOCINE GRINDEKS 5 U.I./1 mL, solution injectable/pour perfusion
	OXYTOCINE GRINDEKS 10 U.I./1 mL, solution injectable/pour perfusion
Germany	Ofost 5 I.E./ml Injektions-/Infusionslösung
	Ofost 10 I.E./ml Injektions-/Infusionslösung
Hungary	Oxytocin Grindeks 5 NE/ml oldatos injekció vagy infúzió
	Oxytocin Grindeks 10 NE/ml oldatos injekció vagy infúzió
Ireland	Ofost 5 IU/ml concentrate for solution for infusion or solution for intramuscular injection
	Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection
Italy	Ossitocina Pharmexon 5 IU/ml soluzione iniettabile/per infusione
	Ossitocina Pharmexon 10 IU/ml soluzione iniettabile/per infusione
Latvia	Ofost 10 SV/ml šķīdums injekcijām/infūzijām
Lithuania	Ofost 5 TV/ml injekcinis ar infuzinis tirpalas
	Ofost 10 TV/ml injekcinis ar infuzinis tirpalas
Poland	Oxytocin Grindeks, 8,3 mikogramów/ml, roztwór do wstrzykiwań/do infuzji
	Oxytocin Grindeks, 16,7 mikrogramów/ml, roztwór do wstrzykiwań/do infuzji

Portugal	Oxitocina Kabi 5 UI/ml solução injetável ou para perfusão
	Oxitocina Kabi 10 UI/ml solução injetável ou para perfusão
Romania	Ofost 8,3 micrograme/ml soluție pentru injectabilă/perfuzabilă
	Ofost 16,7 micrograme/ml soluție pentru injectabilă/perfuzabilă
Slovakia	Ofost 5 IU/ml injekčný/infúzny roztok (injekcia/infúzia)
	Ofost 10 IU/ml injekčný a infúzny roztok (injekcia/infúzia)
Slovenia	Ofost 5 i.e./ml raztopina za injiciranje/infundiranje
	Ofost 10 i.e./ml raztopina za injiciranje/infundiranje
Spain	Oxitocina Kabi 5 UI/ml solución inyectable y para perfusión EFG
	Oxitocina Kabi 10 UI/ml solución inyectable y para perfusión EFG

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