

PATIENT INFORMATION LEAFLET

Oxytocin Injection BP-Oxynir

Oxytocin BP

Read all of this leaflet carefully before you start taking using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider or pharmacist.

In this leaflet:

- a) What Oxynir is and what it is used for
- b) Before you use Oxynir
- c) How to use Oxynir
- d) Possible side effects
- e) How to store Oxynir
- f) Further information

a) WHAT OXYNIR IS AND WHAT IT IS USED FOR

Oxynir contains a manufactured form of oxytocin (a natural hormone). It belongs to a group of medicines called oxytocics that make the muscles of the womb contract.

Oxynir is used:

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

b) BEFORE YOU USE OXYNIR

Do not use OXYNIR

- if you are allergic to oxytocin or any of the ingredients of this medicine.
- if your doctor thinks that to start or increase contractions of the womb would be unsuitable for you, for example:
 - where contractions of the womb are unusually strong
 - where there are obstructions that may prevent delivery
 - 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). Oxynir should not be used for 6 hours after vaginal prostaglandins as the effects of both medicines may be increased.
- Oxynir should not be used for prolonged periods if
 - your contractions do not increase with the treatment
 - you have a condition known as severe pre-eclampsia (high blood pressure, protein in the urine)

and swelling)

- you have severe problems with your heart or blood circulation.

Warnings and precautions

Oxynir should only be administered by a healthcare professional in a hospital setting.

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

Before you receive Oxynir tell your doctor or midwife if:

- 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 Oxynir')
- you have had a previous caesarean section.
- you are more than 35 years old.
- you have raised blood pressure or heart problems.
- your womb was contracting strongly but has now begun to contract less strongly.
- you have been told by a doctor or midwife that normal delivery may be difficult for you due to the small size of your pelvis.
- you have kidney problems, as Oxynir can cause water retention.
- you have had complications during your pregnancy.
- you are more than 40 weeks pregnant.

When Oxynir is given to induce and enhance 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. Oxynir may rarely cause disseminated intravascular coagulation which causes symptoms including abnormal blood clotting, bleeding and anemia. High doses of Oxynir may force amniotic fluid from your womb into your blood. This is known as amniotic fluid embolism. Large doses of Oxynir 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.

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

Latex allergy

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

Other medicines and Oxynir

Tell your doctor or midwife if you are taking or have recently taken any of the following medicines as they may interfere with Oxynir:

- prostaglandins (used to start labour or to treat stomach ulcers) and similar drugs as the effects of both drugs may be increased
- medicines that can cause an irregular heartbeat, as Oxynir may increase this effect
- anaesthetics which you breathe in (e.g. to put you to sleep during surgery), such as halothane, cyclopropane, sevoflurane or desflurane) as these may weaken your contractions, or cause problems with your heartbeat
- anaesthetic medicines for local or regional pain relief, in particular an epidural for pain relief during labour. Oxynir may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

Please tell your doctor or midwife if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Oxynir with food and drink

You may be told to keep the amount of fluids you drink to a minimum.

Pregnancy and breast-feeding

Based on wide experience of use and the nature of this medicine, it is not expected that Oxynir would be a risk to your baby when used correctly. Oxynir 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.

Driving and using machines

Oxynir can start labour. Women with contractions should not drive or use machines.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per 1ml, that is to say essentially 'sodium-free'.

c) HOW TO USE OXYNIR

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

Oxynir is usually diluted before use and given as an intravenous infusion (drip) into one of your veins.

The usual dose is different in the following circumstances:

To start or help contractions during labour

The rate of infusion will start at 2 to 8 drops per minute. This may be gradually increased to a maximum rate of 40 drops 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 5 IU the attempt to start labour should be stopped and then repeated the following day.

Miscarriage

The dose is 5 IU by infusion into a vein. In some cases, this may be followed by a drip at 40 to 80 drops per minute.

Caesarean section

The dose is 5 IU by infusion into a vein immediately after delivery of your baby.

Prevention of bleeding after delivery

The dose is 5 IU by infusion into a vein after delivery of the placenta.

Treatment of bleeding after delivery

The dose is 5 IU by infusion into a vein. In some cases, this may be followed by a drip containing 5 to 20 IU of oxytocin.

Elderly (65 years and over)

There is no information on use in elderly patients. Oxynir is not intended for use in the elderly.

Children and adolescents

There is no information on use in children (2-11 years) or adolescents (12-17 years). Oxynir is not intended for use in children or adolescents.

Patients with kidney disease

There is no information on use in patients with kidney disease. However, you should tell your doctor if you suffer from kidney problems.

Patients with liver disease

There is no information on use in patients with liver disease.

What to do if you receive more Oxynir

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 leftover medicines or the empty packet to the doctor.

An overdose of Oxynir could cause:

- very strong contractions of your womb.
- damage to your womb which could include tearing.
- the placenta to come away from your womb.
- amniotic fluid (the fluid around the baby) to enter your bloodstream.
- harm to your baby.

What to do if you miss a dose

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

d) POSSIBLE SIDE EFFECTS

Like all medicines, Oxynir can cause side effects, although not everyone gets them. Your doctor may consider it necessary to treat the side effects of Oxynir with other medicines. Some side effects could be serious. If any of the following occur, tell your doctor straight away: The following side effect

may affect between 1 and 10 in every 10,000 patients:

- 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.
- Swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema).

The following side effects have been reported in Oxynir Common side effects (more than 1 in 100 patients) of Oxynir include:

- feeling or being sick
- headache
- fast or slow heartbeat

Uncommon side effects (more than 1 in 1,000 patients) of Oxynir include:

- an irregular heartbeat.

Rare side effects (more than 1 in 10,000 patients) of Oxynir include:

- skin rashes

Other side effects

Effects in the mother:

- hemorrhage (bleeding)
- 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
- sudden brief sensation of heat often over the whole body
- abnormal clotting, bleeding and anemia
- 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 side effects, talk to your doctor or pharmacist. You can also report side effects directly to info@aculife.co.in.

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

e) HOW TO STORE OXYNIR

Keep this medicine out of the sight and reach of children. The hospital pharmacy will store this medicine in a refrigerator between 2° to 8°C and make sure that it is not used after the expiry date on the pack. The expiry date refers to the last day of that month.

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (15 °C to 25 °C). 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 are the responsibility of the user.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

f) FURTHER INFORMATION

What Oxynir contains

The active substance is oxytocin BP. There is 10 IU of oxytocin in each milliliter.

The other ingredients are Chlorobutanol BP, Sodium Chloride BP, Anhydrous Sodium Acetate USP & Glacial Acetic acid BP.

What Oxynir looks like and contents of the pack

Oxynir is a Clear, Colorless liquid. The product is filled in 1 ml glass Ampoule USP Type I.

Holder of Certificate of Registration

Aculife Healthcare Pvt. Ltd.

Village: Sachana, Taluka:- Viramgam,

District: Ahmedabad – 382150,

Gujarat, India.

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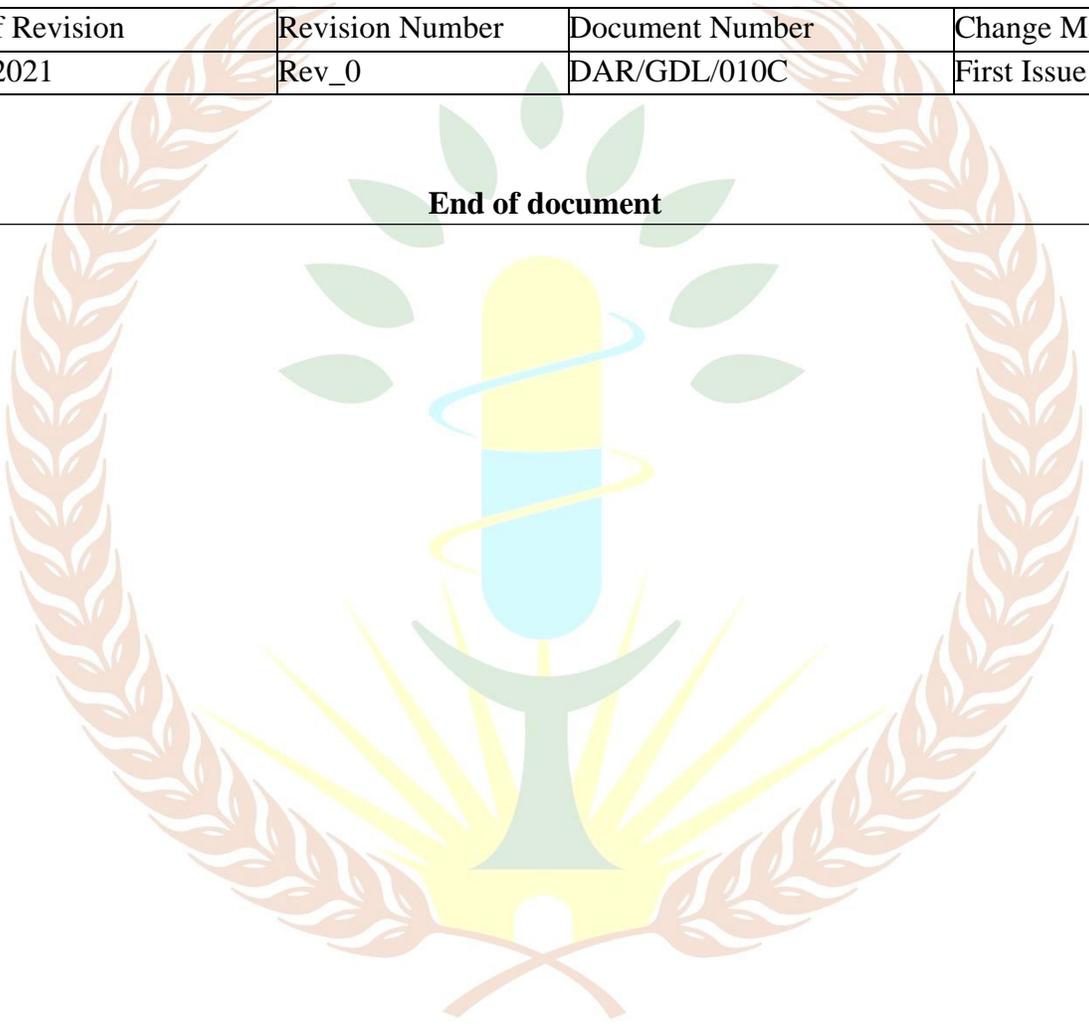
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3.DOCUMENT REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change Made
01/05/2021	Rev_0	DAR/GDL/010C	First Issue

End of document

The logo of the Rwanda Food and Drugs Authority (FDA) is centered on the page. It features a stylized yellow and blue capsule with a blue and yellow spiral around it, set against a green leafy background. Below the capsule is a green mortar and pestle. The entire emblem is framed by a circular wreath of golden-brown wheat stalks. At the bottom of the wreath, there are yellow sunburst rays.

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Rwanda Food and Drugs Authority

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