Package Leaflet: Information for the use

Nife-par 5 mg / ml Oral Solution

Nifedipine

Read all of this leaflet carefully before you start taking the medicine, because it contains important information for you.
- Keep this leaflet as you may need to read it again.
- If you have any further questions, ask your Doctor or pharmacist.
- This medicine has been prescribed for you only, and you should not pass it on to other people, even if they have the same symptoms as you, as it may harm them.
- If you experience side effects, consult your doctor or pharmacist even if it is about side effects that does not appear in this leaflet. See section 4.

Package leaflet content:

1. What Nife-par 5 mg/ml oral solution is and what it is used for

The active substance of Nifedipine, has a marked relaxing action on the smooth muscle tissue of the uterine walls.

Nife-par is indicated for delaying imminent preterm labor in pregnant women with:
- Regular uterine contractions lasting at least 30 seconds and with frequency greater or equal to 4 contractions every 30 minutes.
- Cervical dilation of 1 to 3 cm (0 to 3 cm in first-time women) and removal of the cervix in more than 50%.
- Gestational age from 24 to 33 completed weeks.
- Normal fatal heart rate.

This medicine is for hospital use.

2. What you need to know before you take Nife-par 5 mg/ml oral solution

Do not take Nife-par**:**
- If you are allergic to Nifedipine or to any of the other ingredients of this medicine (listed in section 6).
- If you are being treated with Rifampicin.
- If you are in the first 24 weeks of pregnancy, or in case of:
  - Premature rupture of the membranes after 30 weeks of gestation
  - Fetal growth retardation and abnormal fetal heart rate
  - Antepartum uterine hemorrhage requiring immediate delivery
  - Death of the fetus
  - Suspicion of intra-uterine infection
  - Premature detachment of the placenta
  - Any other condition of the mother or fetus for which the continuation of the pregnancy is dangerous
- If you are in cardiovascular shock (the heart has been so damaged that it is unable to supply enough blood to the body's organs), unstable angina pectoris or if you have recently had an acute myocardial infarction.
- If you have severe hypotension, manifest heart failure and severe obstruction of the aortic valve (a part of the heart).

Warnings and precautions

Take special care with Nife-par
- If you suffer from liver disease
- If you have diabetes
- In case of pre-eclampsia
- It is recommended to monitor maternal blood pressure and uterine function during administration

Taking Nife-par with other medicines

Tell your doctor or pharmacist if you are using, or have recently used or might take any other medicines. Certain medications can interact with Nife-par; in these cases, your doctor will need to adjust the dose or stop the treatment with any of the medicines. This is especially important in the case of taking:
- Antibiotics, such as rifampicin, erythromycin, quinupristin or dalfopristin
- Antiepileptics, such as phenytoin, phenobarbital or carbamazepine; valproic acid
- Antidepressants, such as fluoxetine or nefadozone
- Antifungals (against fungi), such as ketoconazole, itraconazole or fluconazole
- Antiretroviral drugs, such as indinavir, ritonavir, saquinavir, amprenavir, nelfinavir, delarvidene
- Medicines to reduce high blood pressure, such as diltiazem
- Immunosuppressive drugs, such as tacrolimus
- Cimetidine (medicine to treat stomach ulcers)
- Cisapride (medicine for heartburn)

Taking Nife-par with food and drink

Don't drink grapefruit juice during treatment with Nifedipine.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking a medicine. Nife-par is contraindicated during the first 24 weeks of pregnancy.

Nifedipine is excreted in human milk. As a precaution, breastfeeding should be started 36 hours after the last administration.

Driving and using machines

Not applicable

Nife-par contains ethanol, yellow-orange dye and ethyl p-hydroxybenzoate

This medicine contains 44% ethanol (alcohol), which corresponds to 0.88 g per 2.0 ml dose, which is equivalent to 17 ml of beer or 7 ml of wine.

This medicine is harmful for those suffering from alcoholism.

Alcohol content should be considered for pregnant or lactating women, children, and high risk populations, such as patients with liver disease or epilepsy.

This medicine can cause allergic reactions because it contains yellow-orange dye (E-110). My cause asthma, especially in patients allergic to acetylsalicylic acid.

May cause allergic reactions (possibly delayed) because it contains ethyl p-hydroxybenzoate.

3. How to take Nife-par 5 mg / ml oral solution

Follow exactly the instructions of administration of this medicine indicated by your doctor. If in doubt, ask your doctor or pharmacist.

The route of administration is oral. Your doctor will determine the appropriate dose for your particular case.

The recommended dose is:

Initial dose (first hour):

- 2, 0ml (10.0 mg of nifedipine)
- If the contractions do not subside, administer a new dose of 1.5 ml (7.5 mg of nifedipine) after 15 minutes. This new 1.5 ml dose can be repeated every 15 minutes until the contractions subside. The maximum dose during the first hour is 8 ml (40 mg).

Once the contractions have subsided and 6 hours after the last dose administered, the following schedule will continue:
Maintenance dose (next 6 – 48 hours):

- 3ml (15 mg of nifedipine), every 6 – 8 hours, according to response. The maximum daily dose is 32 ml/day (160 mg of nifedipine).

The duration of treatment will be 48 hours, and it may be extended depending on the evolution of the risk of the threat of premature birth, but in principle it should not exceed 72 hours (3 days).

Instructions for the correct administration of the solution open the bottle and insert the syringe, included in the package, pressing into the hole of the perforated cap. Invert the bottle and withdraw the required dose.

If you take more nife-par than you should
If you have taken more nife-par than you should, immediately consult your doctor indicating the medicine and the amount taken.

If you forget to take nife-par
Don't take a double dose make up for a forgotten dose.

If you stop taking nife-par
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everyone gets them. Common at least 1 in 100 patients:

- Headache, dizziness
- Edema (swelling) and vasodilation (dilation of blood vessels).
- Constipation, nausea
- Feeling unwell

Uncommon: (at least 1 in 1000 patients)

- Allergic reaction: allergic edema of the skin and mucosa (swelling) of the larynx.
- Anxiety reactions, sleep disturbances, agitation, and nervousness.
- Vertigo, migraine and tremor.
- Vision disturbance
- Tachycardia (fast heart rate), palpitations, angina pectoris
- Hypotension, postural hypotension, fainting
- Epistaxis (nose bleeding), nasal congestion, dyspnea (shortness of breath), chest pain
- Abdominal and gastrointestinal pain, dyspepsia (difficult digestion), flatulence (gas), dry mouth, diarrhea
- Alteration of the results of liver function tests
- Rash, sweating
- Muscle cramps, joint swelling
- Increased secretion and emission of urine
- Nonspecific pain (pain of unknown cause), chills, asthenia (weakness)

Rare: (at least 1 in 10,000 patients):

- Tingling sensation in the extremities, increased sensitivity to touch
- Gingival hyperplasia (increased thickness of the gums)
- Bloating, poor appetite, vomiting
- Muscle pain

Very rare: (Less than 1 in 10,000 patients)

- Hypotension that can cause heart problems.
- Agranulocytosis, purpura (alternation of certain parameters of the blood).
- Hyperglycemia (disturbance of the blood glucose test).
- Exfoliative dermatitis (peeling of the skin), photosensitivity dermatitis (exaggerated response of the skin to sunlight), urticarial. Cases of acute lung edema have been described (frequency unknown).

A meta-analysis of clinical trials performed with nifedipine as a tocolytic showed that the incidence of adverse reactions was significantly higher with total daily doses exceeding 60 mg.

Communication of adverse effects
If you experience any kind of side effect, consult your doctor or pharmacist, even if it is about possible side effects that are not listed in the leaflet. You can also communicate them directly through the Spanish Pharmacovigilance system for medicines for Human use. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nie-par oral solution
Keep this medicine out of the sight and reach of children. Keep the bottle in the carton to protect them from light.
There is no need of a specific preservation temperature to this medicine.
Don't use this medicine after the expiry date which is stated on the cartoon after"EXP". The expiration date is the last day of the month indicated.
Medicines must not be disposed of via wastewater or household waste. Unused solution must be disposed of in accordance with local requirements. This way you will help to protect the environment.

6. Contents of the pack and other information
what Nife-par contains

- The active substance is nifedipine. Each ml of solution contains 5 mg of nifedipine.
- The other ingredients are 96° ethanol, glycerol, sodium cyclamate (E-952), sodium saccharin (E-954), ethyl p-hydroxybenzoate (E-214), 37% hydrochloric acid (for pH adjustment), orange-yellow dye (E-110), lemon essence and purified water.

What the product looks like and contents of the pack
Amber glass bottle with screw cap and obstructor plus syringe for oral use. Each bottle contains 30 ml of oral solution.

Marketing Authorization Holder and manufacturer in Spain:
LABORATORIO REIG JOFRE, S.A.
Gran Capitán, 10
08970 Sant Joan Despí (Barcelona)

Detailed and updated information on this medicine is available on the website of the Spanish Agency for Medicines and Health Products (AEMPS) http://www.aemps.es/

REIG JOFRE