

NESP[®] INJECTION PLASTIC SYRINGE

10µg/0.5ml, 20µg/0.5ml, 30µg/0.5ml, 40µg/0.5ml, 60µg/0.5ml, 120µg/0.5ml, 180µg/0.5ml
Darbepoetin Alfa (Genetical Recombination)

What is in this leaflet

1. What NESP is and what it is used for
2. Before you use NESP
3. How to use NESP
4. Possible side effects
5. How to store NESP
6. Further information

What NESP is used for

NESP is indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis

How NESP works

NESP works in exactly the same way as the natural hormone erythropoietin. Erythropoietin is produced in your kidneys and encourages your bone marrow to produce more red blood cells. The active substance of NESP is darbepoetin alfa produced by gene-technology in Chinese Hamster Ovary Cells (CHO-K1).

Before you use NESP

When you must not use it

Do not use NESP if you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines

Before you start to use NESP

Tell your doctor and pharmacist:

- If you have a history of myocardial infarction, pulmonary infarction or cerebral infarction.
- If you have hypertension
- If you are pregnant or breastfeeding.

Taking other medicines

- Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.

How to use NESP

How much to use

- Please follow the dosage prescribed by your doctor. If you use this medicine for the first time or for the first time in a long time, you may be administered lower dose intravenously or subcutaneously and observed whether any abnormalities occur.

When to use it

- For hemodialysis patients: In general, for adults, inject intravenously once per week or once every two weeks.
- For patients with chronic kidney disease not on dialysis and peritoneal dialysis patients: In general, for adults, inject subcutaneously or intravenously once every two or four weeks.

How long to use it

- You will be administered this medicine over a long time and the efficacy of this medicine will be observed.

If you forget to use it

- If you have forgotten a dose of NESP, you should contact your doctor to discuss when you should inject the next dose.

If you use too much (overdose)

- You could have serious problems if you take more NESP than you need, such as very high blood pressure. You should contact your doctor, nurse or pharmacist if this does happen. If you feel unwell in any way you should contact your doctor, nurse or pharmacist immediately.

While you are using NESP

Things you must do

- You need to take iron to get an adequate efficacy. If you are prescribed iron, you should take it as instructed by your doctor

Things you must not do

- Do not inject NESP with other products.

Things to be careful of

- You may develop hyperkalemia due to use of this medicine. You need to follow adequate dietary control.
- If you are a patient with chronic kidney disease not on dialysis, seek direction for optimal water intake from your doctor or pharmacist and follow their instruction.

Side effects

The most commonly reported adverse reactions include increased blood pressure, shunt thrombosis/occlusion, headache and malaise. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse effects indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- paralysis of face and limbs on one side, numbness, language disorder such as inarticulateness [cerebral infarction]
- headache, dizziness, nausea [cerebral hemorrhage]
- general malaise, loss of appetite, yellowing in skin and white of eyes [hepatic function disorder, jaundice]
- headache, disturbed consciousness, convulsion [hypertensive encephalopathy]
- urticaria, dyspnea, lip edema, pharyngeal edema (swelling of lips or throat) [shock, anaphylactoid reaction]
- pallor, general malaise, palpitation or shortness of breath in climbing up stairs or walking up a slope [pure red-cell aplasia]
- chest pain, cold sweat, chest pressure [myocardial infarction]
- chest pain, dyspnea, disturbed consciousness [pulmonary infarction]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of NESP

Storage

- Store in a lightproof container at 2-8 °C and avoid freezing.
- Do not use after the expiration date indicated on the package.

Disposal

- The used prefilled syringe should be disposed of in accordance with local requirements.

Product description

What it looks like

It is a colorless and clear solution for injection in a prefilled syringe.

Ingredients

- The active substance is Darbepoetin Alfa (genetical recombination). The prefilled syringe contains 10, 20, 30, 40, 60, 120 or 180 µg of Darbepoetin Alfa (genetical recombination).
- The other ingredients are Polysorbate 80, L-methionine, Sodium Dihydrogen Phosphate Dihydrate, Sodium Chloride and Dibasic Sodium Phosphate Hydrate

MAL No.

NESP® Injection Plastic Syringe 10 µg/0.5ml : MAL XXXX
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NESP® Injection Plastic Syringe 180 µg/0.5ml : MAL XXXX

Manufacturer

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Marketing Authorisation Holder

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