

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

Active Ingredient/generic name: Darbepoetin Alfa (Genetical Recombination)

What is in this leaflet

1. What NESP is and what it is used for
2. How NESP works
3. Before you use NESP
4. How to use NESP
5. While you are using NESP
6. Possible side effects
7. Storage and Disposal of NESP
8. Product description
9. Manufacturer
10. Product Registration Holder
11. Date of revision
12. Serial Number

What NESP is and what it 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

NESP is also indicated for anemia with myelodysplastic syndrome

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 effect. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.

How to use NESP

- **How much to use**

- For all patients: Please follow the dosage prescribed by your doctor.
- For patients with chronic renal failure, including patients on dialysis and not on dialysis: 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.
- For patients with myelodysplastic syndrome: In general, inject subcutaneously once weekly.

- **How long to use it**

- You will be administered this medicine over a long time and the efficacy of this medicine will be observed.
- For patients with myelodysplastic syndrome: If the desired improvement in anemia is not obtained or anemia is aggravated after administration of NESP, change to another treatment should be considered. The necessity of continued administration of NESP should be assessed at approximately 16 weeks after the initiation of administration.

- **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**

- If you are a patient with chronic renal failure, including patients on dialysis and not on dialysis, 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.

Possible 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.

Serious skin reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in association with epoetin treatment. SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-

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threatening complications. If you develop a serious rash or another of these skin symptoms, stop taking NESP and contact your doctor or seek medical attention immediately.

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- 78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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

- Active ingredient(s)**
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).
- Inactive ingredient(s)**
The other ingredients are Polysorbate 80, L-methionine, Sodium Dihydrogen Phosphate Dihydrate, Sodium Chloride and Dibasic Sodium Phosphate Hydrate

MAL number:

NESP[®] Injection Plastic Syringe
10µg/0.5ml : MAL14115034ACZ

NESP[®] Injection Plastic Syringe
20µg/0.5ml : MAL14115030ACZ

NESP[®] Injection Plastic Syringe
30µg/0.5ml : MAL14115031ACZ

NESP[®] Injection Plastic Syringe
40µg/0.5ml : MAL14115035ACZ

NESP[®] Injection Plastic Syringe
60µg/0.5ml : MAL14115026ACZ

NESP[®] Injection Plastic Syringe
120µg/0.5ml : MAL14115032ACZ

NESP[®] Injection Plastic Syringe
180µg/0.5ml : MAL14115033ACZ

Manufacturer

Terumo Corporation, Kofu Factory
1727-1, Tsuijirai, Showa-cho
Nakakoma-gun, Yamanashi, Japan

Product Registration Holder

DKSH Malaysia Sdn Bhd

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KKAPMY/P-EG/NP/1911

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28/03/2025

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