

PATIENT INFORMATION LEAFLET

LIFE-EXTEND 60 mg/ml dextran 70 + 75 mg/ml sodium chloride solution for I.V. infusion

Used intravenously

Sterile

- **Active ingredients:** Each 100 ml solution contains 6 g dextran 70 and 7,5 g sodium chloride
- **Excipients:** Water for injection

Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.

- *Keep these PATIENT INFORMATION LEAFLET. You may need to re-read it later.*
- *In case you have additional questions, please consult your doctor or pharmacist.*
- *This drug is prescribed personally for you, do not give to others.*
- *During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Please follow these instructions strictly. Do not use dosages **higher or lower** than the dosage recommended to you.*

The following topics are included in this PATIENT INFORMATION LEAFLET:

- 1. What is LIFE-EXTEND and what is it used for?**
- 2. Before you are given LIFE-EXTEND**
- 3. How you will be given LIFE-EXTEND?**
- 4. Possible side effects**
- 5. How to store LIFE-EXTEND**

1. What is LIFE-EXTEND and what is it used for?

- LIFE-EXTEND, is a sterile solution prepared for intravenous administration. It contains active ingredients called dextran 70 and sodium chloride. The solution is contained in a 250 milliliter PP bag.
- The product is a plasma substitute which quickly increases the circulating volume in the blood system and helps raise blood pressure.

- LIFE-EXTEND, is used in the initial treatment in case of blood loss due to sudden physical damage and decreased blood volume accompanied by low blood pressure.

2. Before you are given LIFE-EXTEND

DO NOT USE LIFE-EXTEND under following conditions:

If;

- you are known to be hypersensitive to dextran 70, sodium chloride or to any of the other ingredients of the drug
- you are pregnant around the time of delivery

Use LIFE-EXTEND CAREFULLY under following conditions:

If;

- you are already using medicines known to affect blood clotting
- you have a heart disease,
- in certain severe cases if you have diabetes
- you suffer from chronic renal failure

It is, however, obvious that in the acute situation when LIFE-EXTEND is used, this information may often not be known to the doctor. If these conditions are suspected, the potentially higher risks should be observed by the doctor and weighed against the expected benefit for the patient.

When possible please inform your doctor if you are taking or recently have taken any other medicines, even those not prescribed.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use of LIFE-EXTEND with foods or drinks

It is a drug administered intravenously and does not interact with food and drinks in terms of administration.

Pregnancy

Consult your doctor or pharmacist before using this drug.

There is insufficient data on the use of LIFE-EXTEND in pregnant women. LIFE-EXTEND should not be used in pregnant women close to birth and at birth.

In case you become aware that you are pregnant during treatment, immediately consult your doctor or pharmacist.

Lactation

Consult your doctor or pharmacist before using this drug.

It is not known whether this drug passes into breast milk.

Driving and use of machines

It is not applicable.

Important information about some ingredients of LIFE-EXTEND

This medicinal product contains 7.37 g sodium per 250 ml. This should be considered for patients on a controlled sodium diet.

Taking other medicines

This solution should not be mixed with other drugs, as there is no data on incompatibility.

Tell your doctor if you are taking medicines that affect blood clotting. Your doctor will perform the necessary tests and consider this situation.

If you are currently using any prescribed drug or OTC, or if you have used them recently, please inform your doctor or pharmacist about these.

3. How LIFE-EXTEND will be given?

- **Instructions for proper use and dosage/application intervals:**

After the control of respiration and bleeding, 250 ml intravenously is administered as a single dose as an initial treatment.

- **Route and method of administration:**

It is administered through intravenously. It is given intravenously dropwise (whole dose within 2-5 minutes).

- **Different age groups**

Pediatric use:

There are no studies on its use in children.

Use in the elderly:

There are no studies on its use in the elderly .

- **Conditions of special use:**

Renal impairment:

It should not be used in patients with renal impairment.

Hepatic impairment:

Since there is no specific study for this group of patients, there is no specific dosage recommendation for this group of patients.

If you have the impression that the effects of LIFE-EXTEND are too powerful or too weak, consult your doctor or pharmacist.

In case you have used greater amount of LIFE-EXTEND then you should:

Since it is administered as a single dose, it is unlikely that you will use more than you need from LIFE-EXTEND.

Consult a doctor or a pharmacist if you had used LIFE-EXTEND in an amount more than you should.

In case you forget to take LIFE-EXTEND:

Do not take double dosage to balance the skipped dosage.

Possible effects related to the termination of the treatment with LIFE-EXTEND :

The symptoms that may occur with discontinuation of the drug are unknown.

4. Possible side effects

Like all medicines, side effects can occur in people who are sensitive to the ingredients of LIFE-EXTEND. As a result of the use of LIFE-EXTEND: side effects can occur such as fever, nasal congestion (nasal congestion), joint pain, itchy rash (urticaria), hypotension (low blood pressure), chest stiffness, bronchospasm (stenosis of the lower respiratory tract), intravascular coagulation (diffuse intravascular coagulation) kidney, failure and allergic reactions, anaphylactic shocks (severe allergic conditions with rapid breathing effects, itchy blisters on the skin, redness), nausea and vomiting, pain around the infusion site.

If you encounter any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. How to store LIFE-EXTEND

Store LIFE-EXTEND in places out of sight and reach of children and within the original packaging.

Keep at temperatures under 25°C.

This drug is for single use. Partially used bags must not be kept.

The bag should be used immediately after opening.

Do not use if the solution is turbid or the packaging is damaged.

Use this drug according to the expiry date.

Do not use LIFE-EXTEND after the expiry date indicated on the packaging.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisation Holder & Manufacturer:

POLİFARMA İLAÇ SANAYİ VE TİC. A.Ş.

Vakıflar OSB Mahallesi, Sanayi Caddesi, No:22/1

Ergene/TEKİRDAĞ/TURKEY

Phone: +90 282 675 14 04

Fax: +90 282 675 14 05

These PATIENT INFORMATION LEAFLET have been approved on 21/01/2019.