

## PATIENT INFORMATION LEAFLET

### **PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE SOLUTION FOR I.V. INFUSION**

**Used intravenously**

**Sterile**

**Active ingredients:** Each one liter of solution contains 9 grams of sodium chloride and 10 grams of DEXTRAN-40.

**Excipients:** Sterile 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 PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE and what is it used for?**
- 2. Before you are given PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE**
- 3. How you will be given PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE?**
- 4. Possible side effects**

## **5. *How to store* PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE**

### **1. What is PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE and what is it used for?**

- The PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE is a clear and colorless solution administered in the intravascular way.
- The PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE is available in 500 and 1000 ml of glass bottles. It has two forms with and without set.
- The PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE is used in treatment of the following conditions:
  - Conditions with slowed down circulation in the capillaries in the body such as shock, burn, blockage in the capillaries due to fat particles in the blood (fat embolism), pancreas inflammation (pancreatitis), abdominal membranes inflammation (peritonitis) and stopped intestinal movements (paralytic ileus) etc.
  - For preventing circulation disorders in the arteries and veins such as gangrene, leg ulcers, Raynaud disease (a kind of vascular disease mostly seen in women) brain vein diseases without bleeding and intravascular clotting after operation and trauma (any impact) (thromboembolic events).
  - For correcting circulation in the peripheral veins on your body and reducing the risk of clotting (thrombosis) in the veins of the vaccinated part (graft) in vascular surgery and plastic surgery.
  - Open-heart surgeries (in addition to the fluid used in heart – lung device).

### **2. *Before you are given* PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE**

**DO NOT USE PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE under following conditions:**

If you had an allergic reaction when you took the drugs containing the active agents or auxiliary agents contained in the PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE previously, namely you had the symptoms of sudden out-breathing, stertorous

respiration, skin rash, itch or swelling on your body etc., do not use this drug. If you are not sure if you have allergy, consult with your doctor.

The solution must not be used in the following conditions:

- If you have a disease of clotting disorder with critical bleeding;
- If you have a serious heart insufficiency developed with fluid in your lungs;
- If you have renal insufficiency with very rare urination or no urination.

**Use PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE CAREFULLY under following conditions:**

- All intravascular administrations must be conducted regularly and under a careful observation. Therefore, your doctor shall follow your clinical condition closely and shall perform blood tests on you in regular intervals. In addition, as it is reported that serious side effects may occur in the earlier periods of the administration, you shall be followed in the first minutes of your treatment with this drug very carefully.
- When it is administered to patients having sodium restriction, it must be noted that the solution contains 154 mEq sodium (salt) per liter. In addition, this drug must be carefully used in other conditions and treatments developed with salt deposit (e.g. corticosteroid treatment).
- It is required to consider the possibility of intravascular volume overload in patients to whom this drug is administered. This drug must be administered to patients whose renal functions disordered, with fluid in their lungs (pulmonary edema) or fluid in the entire body (congestive heart insufficiency).
- This drug must be used for diabetic patients carefully.
- If this drug shall be administered to you through an electronic pump, it must be noted that the pump stopped before full discharge of the bottle.
- It is recommended to replace the pipes (sets) used to administer this drug to you in every 24 hours. In addition, it must be used only if the bottle is sound and solution in it is clear.

If these warnings are applicable to you even in a past period, consult with your doctor.

### **Use of PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE with foods or drinks**

The PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE is a drug administered in a vascular way; it has no interaction with foods and drinks in terms of method of administration.

### **Pregnancy**

*Consult your doctor or pharmacist before using this drug.*

Do not use PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE during pregnancy unless specifically recommended by your doctor.

*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.*

If you are breastfeeding your infant, inform your doctor about this. Do not use PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE during lactation if not specifically approved by your doctor.

### **Driving and use of machines**

PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE has no effects on driving or using machines.

### **Important information about some ingredients of PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE**

No adverse effects are expected related to the inactive ingredients included in the contents of PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE unless you are hypersensitive against such substances.

This medicinal product contains 154 mmol sodium per liter. This should be considered for patients on a controlled sodium diet.

### **Taking other medicines**

If you plan to take, currently taking or have taken recently any other drugs also including OTCs, vaccines or herbal drugs please inform your doctor.

If you take a drug preventing blood clotting (heparin), please inform your doctor that you take this drug or you have taken it recently; there is a risk of bleeding if it is administered with heparin.

PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE is incompatible with some drugs. Such drugs which are known to be incompatible must not be included in the solution.

For minimizing an impermeability risk with any other drug to be added in the solution, the healthcare officer shall control immediately after the mixing process if there is blurriness or settlement in the last mixture to be administered before the administration and in certain intervals during the administration.

*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 PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE will be given?**

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

It is used as 500-1500 ml per day depending on the condition for which it is used for you in general (20 per kilogram of your body weight mostly).

Your doctor shall decide volumes of this drug that you need and time of administration to you. He/she shall decide them depending on your age, body weight and reason of administration of this drug to you. Follow these instructions unless your doctor advises you otherwise.

Do not forget to take your drug in a timely manner.

Your doctor will inform you about the period of your treatment with PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE. Do not stop the treatment earlier, because if you do, you will not obtain the expected results.

- **Route and method of administration:**

This drug is administered to your vein through a proper plastic pipe (set).

- **Different age groups**

**Pediatric use:**

The dosage and the size of the administration for children will be decided by the doctor that recommends the administration.

#### **Use in the elderly:**

If you are old, you may have some problems related to your liver, kidney or heart and you may use other drugs together or you may have diseases other than the condition tried to be treated, therefore treatment shall be started with the lowest effective doses.

- **Conditions of special use:**

#### **Renal/ hepatic impairment**

If you have a problem in respect of your kidneys, this drug shall be administered to you more carefully and its dose shall be adjusted according to your condition if required.

There is no specific information about its use in case of liver insufficiency.

*If you have the impression that the effects of PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE is too powerful or too weak, consult your doctor or pharmacist.*

#### **In case you have used greater amount of PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE then you should:**

*Consult a doctor or a pharmacist if you had used PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE in an amount more than you should.*

#### **In case you forget to take PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE:**

*Do not take double dosage to balance the skipped dosage.*

#### **Possible effects related to the termination of the treatment with PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE:**

None

#### **4. Possible side effects**

Like all drugs, PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE can cause adverse effects in individuals who are sensitive to the contents.

The side effects are listed as shown in the following categories:

Very common      It may be seen in at least 1 of 10 patients.

Common            It may be seen in less than one of 10 patients but in more than one of 100

	patients.
Uncommon	It may be seen in less than one of 100 patients but in more than one of 1000 patients.
Rare	It may be seen in less than one of 1000 patients.
Very rare	It may be seen in less than one of 10000 patients.
Unknown	It may not be estimated based on the available data.

**If any of the followings occurs, stop use of the PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE and inform your doctor immediately or visit the emergency unit of the closest hospital:**

Excessive sensitivity reactions (itch, redness/swelling, sense of sting in the section of drug administration or whole body; respiratory difficulty, stertorous respiration, chest ache; sense of excessive warmth or coldness sense; shake; swelling in hands, feet, lips, face or whole body; headache, dizziness, sense faint; heart throb).

All of them are very serious side effects.

If you have any of them, it means that you have a serious allergy to the PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE. It may require urgent medical intervention or hospitalization.

All of these very serious side effects are seen very rarely.

The following side effects may also be seen other than the excessive sensitivity reactions:

- Those seen in unknown frequency:
  - Symptoms of fever, shake etc. during the administration (febrile reaction).
  - Inflammation in the place of administration, hardness, redness or swelling starting from the place of administration along with your veins.
  - Hives (itchy and swollen plaques on the skin surrounded with redness in a size varying from a few millimeters to a few centimeters and in various forms).
  - Nasal blockage.
  - Slight hypotension.
  - Nausea, vomiting and similar symptoms related to your stomach-intestines.
  - Fever.

- Arthralgia.

All of them are serious side effects. They may depend on your drug or intravascular administration. They may require urgent medical intervention.

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

## **5. How to store PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE**

*Store PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE in places out of sight and reach of children and within the original packaging.*

It must be kept at a temperature below 25°C in a place without taking direct light. It must not be frozen.

This drug is for single use. Partially used bottles must not be kept and must be discarded according to the medical waste procedures of the healthcare organization.

The expiry date is indicated on the label of each bottle. This drug will not be administered to you if this date has expired. **Use this drug according to the expiry date.**

*Do not use PF 100 MG/ML DEXTRAN 40 9 MG/ML ISOTONIC SODIUM CHLORIDE 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 and Manufacturer:** POLİFARMA İLAÇ SAN. VE TİC. A.Ş.

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