PACKAGE LEAFLET: INFORMATION FOR THE USER

BIOFLEKS 20% MANNITOL Solution for Injection

For intravenous use only.

- ***Active ingredient:*** Each 100 ml of solution contains 20 g of mannitol.
- ***Excipients*:** Sterile water for injections.

Before use this medicine, please read this PATIENT INFORMATION LEAFLET carefully, because it contains important for you.

- *Keep this leaflet. 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. Do not pass it on to others*
- *When you go to the hospital during using this medicine, tell your doctor you take this medicine*
- *Follow these instructions exactly. Do not use **higher or lower** doses than recommended dose to you.*

In this leaflet:

1. What BIOFLEKS 20% MANNITOL is and what it is used for?

BIOFLEKS 20% MANNITOL, is a solution **given by infusion into a vein**, contains “mannitol” as active ingredient which has diuretic effect.

BIOFLEKS 20% MANNITOL is used to produce an increase in your urine production which may be decrease due to group of diseases or provide the formation of urine. It also used to reduce pressure in the skull and eye and promotes the excretion of toxic substances from the body by increasing urine flow.

BIOFLEKS 20% MANNITOL is supplied in 100 ml, 150 ml, 250 ml or 500 ml in PVC bags with two outputs with protective HDPE Overpouch. This drug is given by intravenous (into a vein) infusion.

2. What you need to know before you use BIOFLEKS 20% MANNITOL?

You should NOT receive BIOFLEKS 20% MANNITOL if you are suffering from any of the following conditions:

- if you are allergic (hypersensitive) to mannitol or any of the other ingredients of BIOFLEKS 20% MANNITOL. If you are not sure whether you are allergic, consult your doctor.
- if you have a high concentration of salts in your blood (hyperosmolarity).
- if you are severely dehydrated.
- if it is known that your kidneys cannot produce urine.
- if you have severe heart failure.
- if you have fluid on your lungs, arms, legs or entire body (severe oedema).
- if you have bleeding inside the skull.
- if the natural protective barrier between the blood vessels in your head and your brain is damaged.

Use carefully BIOFLEKS 20% MANNITOL for following conditions

If you have or have had any of the following medical conditions:

- Kidney disease or poor kidney function;
- Heart disease or heart failure;
- Lung disease;
- Conditions of shock;

or if you are receiving medicines which may be harmful to your kidneys, your doctor will take special care when giving you BIOFLEKS 20% MANNITOL.

If this medicine administered to you by an electronic pumping device, care must be taken to discontinue pumping action before the container runs dry.

Your doctor or nurse will ensure the solution is clear and container and seals are intact before use.

It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

BIOFLEKS 20% MANNITOL should not be given through the same set as blood transfusion.

Taking BIOFLEKS 20% MANNITOL with food and drink,

Not applicable, since BIOFLEKS 20% MANNITOL is administered by intravenously.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

BIOFLEKS 20% MANNITOL should not be given to pregnant women unless medically justified.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist *immediately*

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

If you are breast-feeding, ask your doctor for advice. Your doctor will therefore only give you BIOFLEKS 20% MANNITOL during breast-feeding if it is clearly needed.

Driving and using machines

BIOFLEKS 20% MANNITOL has no effect on driving or using machines.

Taking other medicines

Please tell your doctor if you are taking, have recently taken or might use any other medicines, including medicines obtained without a prescription and herbal medicines.

Additives may be incompatible with BIOFLEKS 20% MANNITOL. In the absence of compatibility studies this medicinal product must not be mixed with other medicinal products.

Concurrent use of other diuretics (water tablets, to increase the amount of urine you produce) may potentiate the effects of mannitol and dose adjustments may be required.

BIOFLEKS 20% MANNITOL increases the elimination of medicinal products excreted through urine (e.g. lithium and methotrexate) and therefore concomitant use of mannitol may impair the response to these medicinal products.

Concomitant administration of drugs that may cause kidney damage and BIOFLEKS 20% MANNITOL may increase the cumulative toxicity due to fluid imbalance related to mannitol.

Therefore, patients receiving concomitant ciclosporin (a medicine that reduces the activity of the body's immune system) should be closely monitored for signs of these harmful effects.

Although there is limited evidence of following interactions occurring in humans, other potential interactions are:

- Aminoglycosides (a type of antibiotic): potentiation of their harmful effects on hearing by BIOFLEKS 20% MANNITOL.
- Depolarising neuromuscular blocking drugs (used during anaesthesia to cause muscle paralysis): enhancement of their effects by BIOFLEKS 20% MANNITOL.
- Oral anticoagulants (medicines to thin the blood): BIOFLEKS 20% MANNITOL may reduce their effects by increasing the concentration of clotting factors secondary to dehydration (a loss of water from the body)
- Digoxin (a heart medicine): if hypokalemia (*low blood levels of potassium)* follows BIOFLEKS 20% MANNITOL treatment there is a risk of digoxin toxicity.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

3. How to use BIOFLEKS 20% MANNITOL?

Instructions for proper use and dose/frequency of administration:

Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight, condition and the reason for treatment. Follow these instructions unless your doctor tells you otherwise.

Do not forget to take your medication on time.

Your doctor will tell you how long you should take BIOFLEKS 20% MANNITOL. Do not interrupt treatment before being advised, otherwise therapy may not be complete.

Method and route of administration:

BIOFLEKS 20% MANNITOL will usually be given to you through a plastic tube attached to a needle in a vein.

Various age groups:

- **Use in children:**

Your doctor will adjust the dose as necessary.

- **Use in the elderly:**

Since incipient renal insufficiency may be present, caution should be used when reviewing patient's status prior to dose selection.

Special conditions for use:

Renal failure:

If your kidneys are not working properly, your doctor may give you a test dose of the infusion. The amount of urine you produce will then be measured. If your kidneys do not respond well enough, you will be given a different treatment.

If you feel the effect of BIOFLEKS 20% MANNITOL is too strong or too weak, talk to your doctor or pharmacist.

If you receive more BIOFLEKS 20% MANNITOL than you should

If you take too much BIOFLEKS 20% MANNITOL talk to your doctor or pharmacist.

If you forget to use BIOFLEKS 20% MANNITOL

Do not take a double dose to make up for a forgotten dose.

Stopping your BIOFLEKS 20% MANNITOL

Your doctor will decide when to stop giving you this infusion.

4. What are the possible side effects?

Like all medicines, BIOFLEKS 20% MANNITOL can cause side effects, although not everybody gets them.

If you have any of the following side effects while taking your medicine tell your doctor immediately or go to your nearest hospital emergency department.

Uncommon (affects less than 1 in 100, but more than 1 in 1000 patients):

- fluid or electrolyte imbalance in the body

- a low blood pressure (hypotension)
- infusion site inflammation of the vein with redness, swelling and pain along the path of the vein (thrombophlebitis)

Rare (affects less than 1 in 1000, but more than 1 in 10 000 patients):

- a kind of shock condition called "anaphylactic shock" characterized by symptoms such as swelling of hands, feet, lips, face or whole body; difficulty in breathing; wheezing; chest pain; dizziness; fainting; sudden decrease in blood pressure.
- convulsions (seizures)
- an increase in pressure within the skull
- an irregular heartbeat
- fluid on the lung (pulmonary oedema)
- fluid collecting under the skin, usually around the ankles (oedema)
- a high blood pressure (hypertension)
- not enough water in the body (dehydration)
- damage to the kidney (osmotic nephrosis)
- allergic (hypersensitivity) reaction
- hives (urticaria)
- headache
- dizziness
- blurred vision
- cramps
- dry mouth, thirst, nausea, vomiting
- chest pain
- chills, fever
- death of an area of skin (skin necrosis)

Very rare (affects less than 1 in 10 000 patients):

- difficulty in breathing, shortness of breath, especially when lying down, (symptoms of congestive heart failure)
- sudden onset of kidney failure, seen by a marked decrease in urine production.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store BIOFLEKS 20% MANNITOL?

Keep BIOFLEKS 20% MANNITOL out of the reach and sight of children in the original package.

Store at room temperature (< 25°C).

Do not freeze.

For single use only. Any solution remaining after treatment should be disposed of using the approved hospital procedures.

Please use in accordance with expiration date.

Do not use BIOFLEKS 20% MANNITOL *after the expiry date which is stated on the package.*

Marketing Authorization Holder and Manufacturer:

Osel İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Cad. No: 52
Beykoz / İSTANBUL/TURKEY

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

The solution for infusion should be visually inspected prior to use. Use only if the solution is clear, without visible particles and if the container is undamaged.

Administer immediately following the insertion of infusion set.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the re-sealable medication port. When additive is used, verify isotonicity prior to parenteral administration.

Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use. Discard any unused portion. Do not reconnect partially used bags.

To open:

1. Check the outer packaging for leaks. If the container is damaged, discard the solution.
2. Tear open the protective outer packaging.
3. Check for minute leaks by squeezing the inner bag firmly.
4. If solution is not clear or contains foreign matters, discard the solution

Preparation for administration:

1. Suspend container from eyelet support.
2. Twist off protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

Addition of medicinal products:

Caution: As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition.

To add medication before administration:

1. Disinfect medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration:

1. Close clamp on the set.
2. Disinfect medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping gently while the container is in an upright position. Mix solution and medication thoroughly.

Return container to in-use position, re-open the clamp and continue administration.