SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium chloride 0.9% Imuna

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 mL solution for infusion contain:

Sodium chloride	9.0 g

Electrolytes

Sodium	154 mmol/L
Chloride	154 mmol/L

For the full list of excipients, see section 6.1.

2. PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless, solution free of mechanical impurities

Theoretical osmolarity 308 mOsm/L
Titration acidity (pH 7.4) < 0.3 mmol/L
pH 4.5 – 7.0

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short- term intravascular volume substitution.
Hypotonic dehydration or isotonic dehydration.
Vehicle solution for supplementary medication.
Fluid and electrolyte replacement, hypochloremic alkalosis and chloride losses.

4.2 Posology and method of administration

Dosage

The dosage guideline for adults:
Average dose: 1000 ml per day.
Flow rate: Up to 180 drops/min, corresponding to 550 ml/h.
Maximum recommended dosage: 40 ml per KG body weight and per day, not more than 2000 ml per day.
Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determination.

Route of administration
I.V.

4.3 Contraindications

Sodium chloride 0.9 % Imuna may not be used in the event of

- hyperhydration
- severe hypernatraemia.
- severe hyperchloraemia

4.4 Special warnings and precautions for use

Sodium chloride 0.9 % Imuna should be used with caution only in
- hypokalaemia
- hypernatraemia
- hyperchloraemia
- Conditions requiring a restricted intake of sodium, such as heart failure, generalised oedema, pulmonary oedema, hypertension, eclampsia and severe renal failure.

In order to prevent osmotic demyelination syndrome from developing, serum sodium concentrations should not exceed 9 mmol/L/day. As a general recommendation, a rate of correction of 4 to 6 mmol/L/day is considered appropriate in the majority of cases, depending on the patient's conditions and associated risk factors.

Clinical monitoring should include checks of the serum ionogram, water balance and the acid-base balance.

If the rapid infusion of 0.9 % NaCl is required, the cardiovascular and respiratory status should be monitored closely.

Please note: if this solution is being used as a carrier solution, the safety information on the additive provided by the respective manufacturer is to be taken into account.

Children and adolescents

Premature or newborn babies may develop excess sodium levels due to immature kidney function.
Therefore, repeated sodium chloride infusions should only be administered after serum sodium levels have been determined.

4.5 Interactions with other medicinal products and other forms of interaction

Medicinal products leading to sodium retention
The simultaneous use of sodium-retaining medicinal products (e.g. corticosteroids, non-steroidal anti-inflammatory drugs) can lead to oedema.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of Sodium chloride 0.9 % Imuna in pregnant women. Similarly, animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.

Sodium chloride 0.9 % Imuna may therefore be used as stated.

Caution must be exercised, however, in the event of eclampsia (see section 4.4).

Lactation
Sodium chloride is excreted in human milk. Given that the concentrations of sodium and chloride are similar to those found in the human body, no harmful effects are to be expected when the product is used correctly.

Sodium chloride 0.9 % Imuna may be used during lactation if required.

Fertility
No data are available.

4.7 Effects on ability to drive and use machines
Sodium chloride 0.9 % Imuna has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None known if used correctly.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Symptoms
An overdose of Sodium chloride 0.9 % Imuna can lead to hypernatraemia, hyperchloraemia, hyperhydration, acute volume overload, oedema, serum hyperosmolality and hyperchloraemic acidosis.

In patients with chronic hyponatraemia, a rapid rise in the serum sodium concentration can lead to osmotic demyelination syndrome (see section 4.4).

The first signs of overdose may be thirst, confusion, sweating, headache, weakness, drowsiness or tachycardia. Hypertension or hypotension, respiratory failure or coma may occur in the event of severe hypernatraemia.

Management

Depending on the severity of the symptoms, immediate stopping of the infusion and administration of diuretics whilst constantly monitoring serum electrolytes, and correction of electrolyte and acid-base imbalances.

Dialysis may be required in the event of major overdosage or oliguria or anuria.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: solutions affecting electrolyte balance, electrolytes,
ATC code: B05B B01

Mechanism of action
Sodium is the primary cation in the extracellular space and, together with various anions, regulates the size of the latter. Sodium is one of the major mediators of bioelectric processes within the body.

Chloride is the main osmotically active anion in the extracellular space.

A rise in the serum chloride concentration leads to increased renal bicarbonate excretion. An acidifying effect is therefore induced through the administration of chloride.

Pharmacodynamic properties
The sodium content and fluid metabolism in the body are closely connected. Each deviation in plasma sodium from the physiological concentration simultaneously affects the body's fluid status.

Independently of serum osmolality, a rise in the sodium content within the body also means a drop in free body water.

An 0.9 % solution of sodium chloride has the same osmolarity as plasma. Administration of this solution leads primarily to filling of the interstitial space, which represents roughly 2/3 of the whole extracellular space. Only 1/3 of the volume administered remains in the intravasal space. The haemodynamic effect of the solution is therefore only short-lasting.

5.2 Pharmacokinetic properties

Absorption

As the solution is administered as an intravenous infusion, the bioavailability of the solution is 100 %.

Distribution

The body's total sodium content is approximately 80 mmol/kg (5600 mmol), of which 300 mmol can be found in intracellular fluid in a concentration of 2 mmol/L and 2500 mmol of which are bound in bones. Approximately 2 mol can be found in extracellular fluid in a concentration of 135-145 mmol/L (3.1-3.3 g/L).

The total chloride content in the body is approximately 33 mmol/kg bodyweight. Serum chloride ranges from 98 to 108 mmol/L.

Biotransformation

Although sodium and chloride are absorbed, distributed and excreted, they are not metabolised in the strict sense.

The kidneys are the main regulators of sodium and fluid balance. Together with hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and with the hypothetical natriuretic hormone, they are chiefly responsible for keeping the volume of the extracellular space constant and for its fluid composition.

Chloride is exchanged for hydrogen carbonate in the tubule system and, in this way, is involved in the regulation of the acid-base balance.

Elimination
Sodium and chloride are excreted via sweat, urine and the gastrointestinal tract.

5.3 Preclinical safety data

No preclinical studies have been conducted with Sodium chloride 0.9 % Imuna .

Given that sodium and chloride ions are major elements of the human body, Sodium chloride 0.9 % Imuna is not expected to have any toxic effects when used correctly.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

When mixed with other medicinal products, potential incompatibilities should be considered.
A physiological solution is used as the main solvent and a vehicle of parenterally administered medicinal products. Detection of the added medicinal product incompatibility with the Sodium Chloride 0.9 % Imuna solution falls within the physician's responsibility. A physician should inspect potential change in the solution colour and/or the potential presence of a clot, insoluble complexes, or formation of crystals. A physician should also read the manual on the use of the added medicinal product.
Prior to the addition of a medicinal product, it should be verified whether the medicinal product is soluble and stabile in water within the pH range.
Once a compatible medicinal product is added to the Sodium Chloride 0.9 % Imuna solution, the solution must be used immediately.
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.
Keep in the outer package in order to protect from light.
Take the infusion bag out of the outer bag immediately before use. The infusion bag maintains the medicinal product sterility.

6.5 Nature and contents of container

A polyolefin and polypropylene bag with an infusion port and an injection port, with volumes of 100 ml, 250 ml, 500 ml, and 1,000 ml.

The bags are available in the following sizes:

1 x 100 ml, 1 x 250 ml, 1 x 500 ml, 1 x 1,000 ml (individually)
50 x 100 ml, 30 x 250 ml, 20 x 500 ml, 10 x 1,000 ml (in a cardboard box)

Not all pack sizes may be marketed.

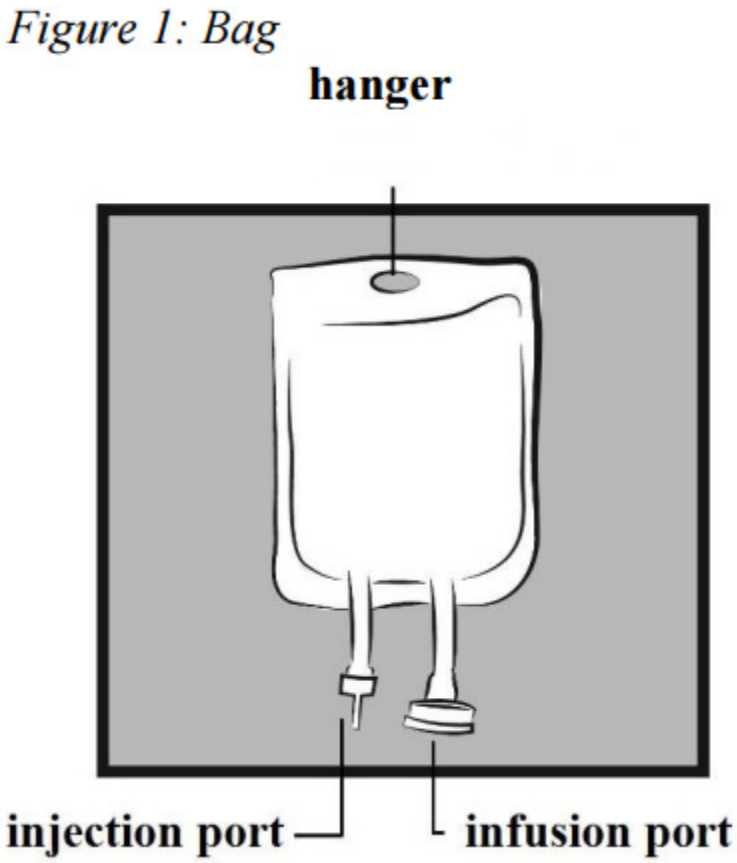
6.6 Special precautions for disposal and other handling

For single use only. Any unused solution should be discarded.
Partially used bags should not be repeatedly attached.
Use only if the solution is clear, free of any visible particles, and if the packaging is intact. Apply immediately once attached to the infusion set.
Do not attach plastic bags in series. Such use may lead to an air embolism caused by drawing the remaining air in from the main bag before the fluid administration from the auxiliary bag is terminated. If the residual air is not fully removed from the bag prior to the administration, squeezing the intravenous solution in a flexible plastic packaging to accelerate the flow rate may cause an air embolism.
The solution must be administered aseptically, using a sterile device. To prevent the air from penetrating the system, the device must be filled up with the solution.

Other medicinal products may be added before or after the infusion administration via a venous line.
If another medicinal product is added to the solution, check the isotonicity prior to the parenteral administration. All added medicinal products must be thoroughly and carefully mixed in an aseptic manner. Solutions containing also other added medicinal products must be used immediately and must not be stored for later use.
For single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Do not reattach partially used bags.
Take the infusion bag out of the outer bag immediately before use. The infusion bag maintains the medicinal product sterility.

BAG MANIPULATION INSTRUCTIONS MANUAL

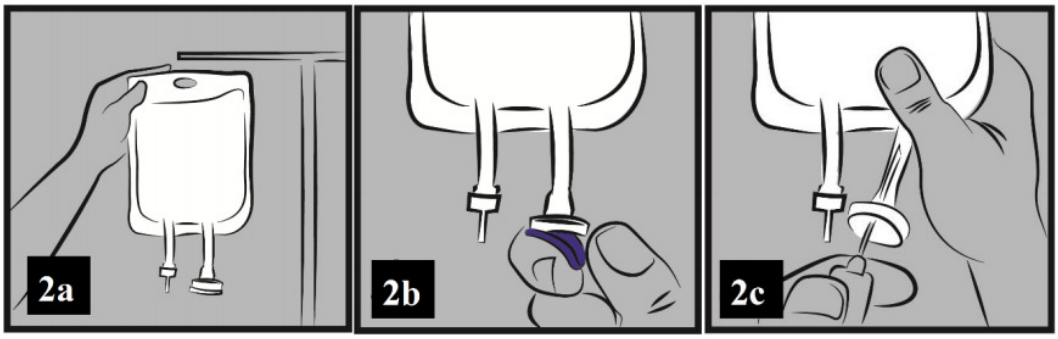
Figure 1: Bag



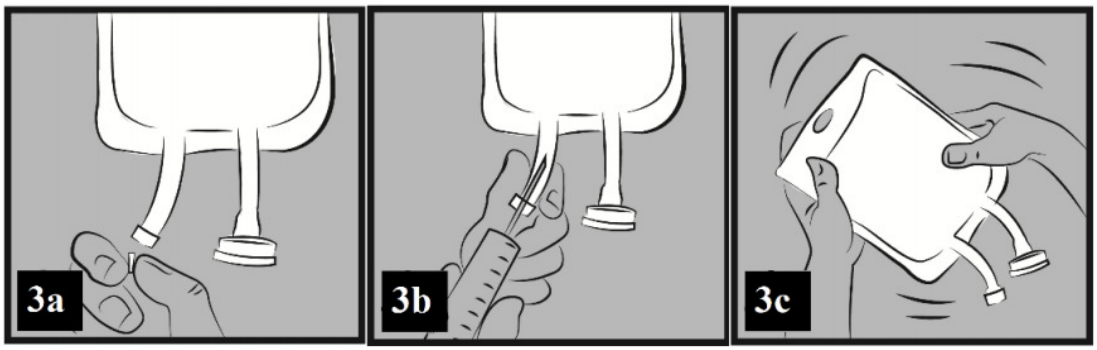
1. INSPECTION PRIOR TO APPLICATION

a) Check the bag for any leakage of fluid. If you observe any bag integrity disruption, discard the bag containing the solution, as its sterility may be impaired.
b) Check visually whether the solution meets the characteristics listed in the Summary of Product Characteristics. If not, the solution should be discarded. Prepare and apply the solution while using sterile materials.

2. PREPARATION FOR THE APPLICATION
a) Hang the bag on a stand or put it on a horizontal surface (Figure 2a).
b) Break off a blue plastic cover from the delivery port (infusion port) (Figure 2b).
c) A rubber cap of the port is sterile, so the disinfection is not required. Attach a thick perforation needle of the infusion set to the infusion port (Figure 2c).
d) Proceed as described in the manual attached to the infusion set (set filling and solution application).



3. ADDING A MEDICINE TO THE SOLUTION
a) Break off a transparent cover on the injection port. A rubber plug is sterile, so the disinfection is not required (Figure 3a).
b) Puncture the injection port and add the medicine. A recommended needle size: 19 G (1.10 mm) to 22 G (0.70 mm) (Figure 3b).
c) Thoroughly mix the bag content (Figure 3c).



Warning: Respect the instructions for the disposal of bags in the healthcare segment (content of the added medicine).

The bag may be filled up with the following maximum amounts of other medicines:

100 ml bag	max. 70 ml
250 ml bag	max. 75 ml
500 ml bag	max. 115 ml
1,000 ml bag	max. 130 ml

7.MANUFACTURER
Imuna Pharm a.s., Jarková 269/17, 082 22 Šarišské Michaľany, Slovak Republic

8. MARKETING AUTHORISATION HOLDER
A.L. Medi-Market Ltd., 3 Hakatif St., Emek Hefer Industrial Park, 3877701, Israel

9. MARKETING AUTHORISATION NUMBER
167-57-36009-00

Revised in March 2022 according to MOH's guidelines.