SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Delefluids Darrow's Half Strength Intravenous Injection

1.1 (Invented) name of the medicinal product

Delefluids Darrow's Half Strength Intravenous Injection

1.2 Pharmaceutical form – Injectable

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantitative Composition

Each 100 ml Contains…

Sodium Lactate	BP 2.35 gm
Sodium Chloride	BP 0.9 gm
Potassium Chloride	BP 0.68 gm
Water for Injection	BP q.s. to 500 ml

3. PHARMACEUTICAL FORM

Injectable

Description

Clear, Colourless transparent liquid contains in 500ml PVC Pouch

4. **Clinical Particulars**

4.1 Therapeutic indications

Darrow's Half Strength I.v Solution is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Hypertension
- Electrolyte imbalance
- Arrhythmias
- Low sodium levels
- Low potassium levels
- Low magnesium levels
- Low calcium levels
- Blood and fluid loss
- Deficiency of potassium

4.2 Posology and method of administration

The choice of Darrow half strength solution concentration, dosage, volume, rate and duration of administration depends on the age, weight, clinical condition of the patient and concomitant therapy. It should be determined by a physician. For patients with electrolyte abnormalities and for paediatric patients, consult a physician experienced in intravenous fluid therapy.

Fluid balance, serum electrolytes should be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of

inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids.

Adults, older patients and adolescents (age 12 years and over):

The recommended dosage is: 500 ml to 3 L/24h

Administration rate:

The infusion rate is usually 40 ml/kg/24h and should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore, the maximum acute administration rate is 5 mg/kg/min.

Paediatric population

The dosage varies with weight:

- 0-10 kg body weight: 100 ml / kg / 24 h
- 10-20 kg body weight: 1000 ml + (50 ml/ kg over 10 kg) / 24h
- > 20 kg body weight: 1500 ml + (20 ml/ kg over 20 kg) / 24h.

The administration rate varies with weight:

- 0-10 kg body weight: 6-8 ml/kg/h
- 10-20 kg body weight: 4-6 ml/kg/h
- > 20 kg body weight: 2-4 ml/kg/h

Precautions to be taken before manipulating or administering the product

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the seal is intact. Administer immediately following the insertion of infusion set. Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

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.

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. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers

4.3 Contraindications

Hypersensitivity to Darrow's Half Strength I.v Solution is a contraindication. In addition, Darrows Half Strength I.v Solution should not be used if you have the following conditions:

- AV Block
- Concomitant digitalis therapy

- Congestive heart failure
- Extracellular hyperhydration
- Hepatic insufficiency
- Hypercalcaemia
- Hyperkalemia
- Hypersensitivity
- Liver cirrhosis
- Newborns less than 28 days of age

4.4 Special warnings and precautions for use

Before using Darrow's Half Strength I.v Solution, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- *Administration of parenteral fluids*
- *Blockage of intestine*
- *Consult a doctor if you have congestive heart failure, hypertension or renal disease*
- *Consult a doctor of you have congestive heart failure*
- *Dehydration*
- *Excess administration*
- *Excessive administration*
- *Geriatric patients*
- *Heart problem*
- *High blood potassium level*

4.5 Interaction with other medicinal products and other forms of interaction

Administration of other drugs or over the counter products at the same time, the effects of Darrow's Half Strength I.v Solution may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Darrow's Half Strength I.v Solution may interact with the following drugs and products:

- Acetaminophen
- Aspirin
- Chlorpheniramine
- Cyclosporine A
- Hydrocodone
- Indomethacin
- Mannitol
- Oxytocin
- Salsalate
- Terbutaline

4.6 Fertility, pregnancy and lactation

Pregnancy: No documented information.

The potential risks and benefits for each specific patient should be carefully considered before administration.

4.7 Effects on ability to drive and use machines

There is no information on the effects of Darrow half Strength solution on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The following is a list of possible side-effects that may occur from all constituting ingredients of Darrow's Half Strength I.v Solution. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Nausea
- Skin rash
- Stomach upset
- Acute toxicity
- Vomiting
- Diarrhea
- Muscular twitching
- Inflammation of the gastrointestinal tract
- Congestion
- Eye irritation
- Stomach pain or swelling
- Black stools
- Numbness or tingling in the skin
- Weak or heavy legs or feet
- Irregular heartbeat
- Cardiac toxicity on rapid infusion
- Confusion or anxiety
- Hands
- Chest pain
- Gas
- Lips
- Muscle weakness or paralysis
- Severe allergic reaction

Darrow's Half Strength I.v Solution may also cause side-effects not listed here.
If you notice other side-effects not listed above, contact your doctor for medical advice. You may also report side-effects to your local food and drug administration authority.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group “Electrolytes with Carbohydrates”,

The pharmacodynamic properties of this solution are those of its components (Potassium, sodium, Lactate and chloride,).

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na^+/K^+-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

Potassium also helps muscles to contract and supports normal blood pressure. In man, mechanisms for potassium excretion are complex and highly developed, while potassium conservation is potentially inadequate. Potassium balance is regulated by alterations in excretion in the distal renal tubule, where mineralocorticoid hormones and Na-K ATPase are the major regulating factors. The distribution of potassium across cell membranes is influenced by changes in acid-base status, by pancreatic hormones and by the autonomic nervous system. Potassium stimulates insulin and aldosterone secretion and increases Na-K ATPase in the distal nephron, so promoting its own redistribution or excretion.

The lactate diffuses out of the cells and is converted to pyruvate and then is aerobically metabolized to carbon dioxide and ATP. The heart, liver, and kidneys use lactate in this manner. Alternatively, hepatic and renal tissues can use lactate to produce glucose via another pathway referred to as gluconeogenesis.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of this solution are those of its components are those as presented above. For example, after injection of radiosodium (^{24}Na), the halflife is 11 to 13 days for 99% of the injected Na and one year for the remaining 1%. The distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurones; it is very slow in the bone. Sodium is predominantly excreted by the kidneys, but (as described earlier) there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical safety data

Preclinical safety data of this solution for infusion in animals are not relevant since its constituents are physiological components of animal and human plasma.

Toxic effects are not to be expected under the condition of clinical application.

The safety of potential additives should be considered separately.

6. Pharmaceutical particulars

6.1 List of excipients
Water for Injections

6.2 Incompatibilities
Incompatibility of the medicinal product to be added with the solution in the PVC container must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products.

The instructions for use of the medicinal product to be added must be consulted.

Before adding a drug, verify it is soluble and stable in water at the pH of Sodium Chloride 0.9% w/v.

As guidance, the medications listed in 4.5 above are incompatible with Darrow half strength solution.

6.3 Shelf life
Unopened: 500 ml bags: 36 months

It is recommended that the product is used immediately once opened

In-use shelf life: Additives

From a physico-chemical viewpoint, solution containing additives should be used immediately unless chemical and physical in-use stability has been established.

From a microbiological point of view, solutions containing additives should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage
No special precautions for storage.

6.5 Nature and contents of container
The bags known as pouch are composed of PVC. The bags are overwrapped with a nylon composed of polypropylene.

The bag size is 500ml

Outer carton contents: 20 bags of 500 ml

6.6 Special precautions for disposal and other handling
Discard after single use.

Do not reconnect partially used bags.

For method of administration and precautions to be taken before handling or administering the medicinal product, please see also section 4.2.

1. Opening

a. Remove the container from the over pouch just before use.

b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.

c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

a. Use sterile material for preparation and administration.

b. Suspend container from eyelet support.

c. Remove plastic protector from outlet port at bottom of container:

• grip the small wing on the neck of the port with one hand,

• grip the large wing on the cap with the other hand and twist,

• the cap will pop off.

d. Use an aseptic method to set up the infusion

e. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible.

To add medication before administration.

a. Disinfect medication site.

b. Using syringe with 19 to 22-gauge needle, puncture resalable medication port and inject.

c. 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. See section 6.3.

1. To add medication during administration

d. Close clamp on the set.

e. Disinfect medication site.

f. Using syringe with 19 to 22-gauge needle, puncture re-sealable medication port and inject.

g. Remove container from IV pole and/or turn to an upright position.

h. Evacuate both ports by tapping gently while the container is in an upright position.

i. Mix solution and medication thoroughly.

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

7. Marketing authorization holder

HMA Medical LTD
Address: KM 3, AFON ROAD, OGBONDOROKO, ILORIN-KWARA STATE

8. Marketing Authorization number(s)

Fresh Application

9. Date of first Authorization/renewal of the authorization

Ongoing

10. Date of revision of the text

N/A

COMPANY CONTACT DETAILS:

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