

SCHEDULING STATUS**S3****PATIENT INFORMATION LEAFLET****ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 127A Solution****ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139A Solution****ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A Solution****ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % Solution**

Read all of this leaflet carefully before you start taking ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE

BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** is and what it is used for

2. What you need to know before you use **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**
3. How to use **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**
4. Possible side effects
5. How to store **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**
6. Contents of the pack and other information

1. What ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % is and what it is used for

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** is a solution used for haemodialysis. Haemodialysis is a procedure which is used to remove the waste products from the body which would otherwise be excreted via the kidneys in urine. The solution corrects the fluid balance and ensures that salt (electrolyte) losses are replaced following treatment.

2. What you need to know before you take ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %

You should not be administered **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**:

- If you are hypersensitive (allergic) to any of the components of **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS**

CONCENTRATE 8.4 % (see **WHAT ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % CONTAINS**).

- If you have an increased level of the electrolyte potassium in your blood (hyperkalaemia).
- If you suffer from a disease affecting the thickness of your blood.

Take special care with ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %

- If your blood pressure is unstable or you have a poor blood circulation, you may experience a severe adverse reaction when using **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**.
- If you have high blood pressure and/or chronic uraemia (accumulation of urinary waste products in your blood) you should use **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** with caution.

Taking other medicines with ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

See Do not take **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**.

- The effects of dialysis and filtration procedures on medicine concentrations in the body can be complex. More medicine may be removed by one dialysis technique than another.
- Your doctor will tell you which medicines you may or may not use in combination with **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and lactation has not been established.

Haemodialysis treatment should be used with particular caution and under the close doctor's supervision.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare

professional for advice before taking this medicine.

Driving and using machines

There is no information for the safety of driving and using machines.

**3. How to take ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and
ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**

Always take **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** will last. If you have the impression that the effect of **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** will last. **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** will only be administered to you in a hospital healthcare professional by a, using a haemodialysis machine. Your doctor will dilute the **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** solution to the correct concentration.

You will not be expected to give yourself **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**. It will be given to you by a person who is qualified to do so. If you have any questions about the proper usage of **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**, ask your doctor.

If you have the impression that the effect of **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** is too strong or too weak, tell your doctor.

If you take more ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % than you should:

Signs and Symptoms

Since a healthcare provider will administer **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**, he/ she will control the dosage. However, in the event of overdosage, your doctor will treat the side effects symptomatically.

If you forget to take ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %:

Since a health care provider will administer **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**, it is unlikely that the dose will be missed.

Your doctor will make sure you receive **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** at the right time.

4. Possible side effects

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** can have side effects.

Not all side effects reported for **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop being dialyzed with **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** and tell your doctor immediately:

- Rash or itching.
- Fainting.

These are all serious side effects. If you have them, you may have had a serious allergic reaction to **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE** and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**. You may need urgent medical attention or hospitalization.

Inform your doctor as soon as possible if you notice any of the following:

- Blood clots in your legs, bleeding
- Dizziness, fits/seizures, light-headedness.
- Nausea, vomiting.
- Muscle cramps.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**5. How to store ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %**

Your doctor or pharmacist is responsible for storing this medicine. They are also responsible for disposing of any unused medicine correctly.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Dilute acidic and alkaline bicarbonate haemodialysis concentrates immediately before use.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilet

6. Contents of the pack and other information

What ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS

CONCENTRATE 8.4 % contains

Each 1000 mL of **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW** contains:

	Acidic Bicarbonate Haemodialysis Concentrate SW 127A	Acidic Bicarbonate Haemodialysis Concentrate SW 139A	Acidic Bicarbonate Haemodialysis Concentrate SW 380A
Sodium Chloride	210,68 g/L	210,68 g/L	210,68 g/L
Potassium Chloride	5,22 g/L	5,22 g/L	5,22 g/L
Calcium Chloride Dihydrate	6,43 g/L	9,01 g/L	7,72 g/L
Magnesium Chloride Hexahydrate	3,56 g/L	3,56 g/L	3,56 g/L
Glacial Acetic Acid	6,31 g/L	6,31 g/L	6,31 g/L
Glucose Monohydrate	38,5 g/L	38,5 g/L	38,5 g/L

Each 1000 mL **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** solution contains:

Sodium Bicarbonate 84,0 g

The other ingredients are purified water and sodium edetate*

* in **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE BIC 8.4 %**

What ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % looks like and contents of the pack

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE's and ALKALINE

BICARBONATE HAEMODIALYSIS CONCENTRATE BIC 8.4 % are clear, colourless

solutions packed into 6 litre and 10 litre translucent high density polyethylene canisters and

are available in the following pack sizes: 6 litre and 10 litre or 2 x 6 litre, packed in a carton.

Holder of Certificate of Registration

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SOUTH AFRICA: 37/34/0090

ZIMBABWE: 2018/23.3.2/5584

ZAMBIA: 506/003L

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139A

SOUTH AFRICA: 37/34/0091

ZIMBABWE: 2018/23.3.2/5582

ZAMBIA: 506/002L

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A

SOUTH AFRICA: 44/32.11/0491

ZIMBABWE: 2018/23.3.2/5583

ZAMBIA: 506/001L

ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %

SOUTH AFRICA: 37/34/0089

ZIMBABWE: 2018/23.3.2/55