PROPOSED PATIENT INFORMATION LEAFLET – CLEAN COPY

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

HIBOR 2500 IU/0,2 ml (SOLUTION FOR INJECTION)

HIBOR 3500 IU/0,2 ml (SOLUTION FOR INJECTION)

Read all of this leaflet carefully before you are given HIBOR:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or professional healthcare specialist.
- **HIBOR** has been prescribed for you personally and you should not share with other people. It may harm them, even if their symptoms are the same as yours.

WHAT HIBOR CONTAINS

HIBOR is a solution for injection.

HIBOR 2500 IU/0,2 ml : Bemiparin sodium 2500 IU (anti Factor Xa *) per 0,2 ml pre-filled syringe (equivalent to 12500 IU (anti Factor Xa *) per millilitre of solution for injection).

HIBOR 3500 IU/0,2 ml contains : Bemiparin sodium 3500 IU
(anti Factor Xa *) per 0,2 ml pre-filled syringe (equivalent to 17500 IU (anti Factor Xa *) per millilitre of solution for injection).

* Potency is described in International anti Factor Xa activity units (IU) of the 1st International Low Molecular Weight Heparin Reference Standard of the WHO.

It also contains water for injection.

WHAT HIBOR IS USED FOR

HIBOR 2500 IU/0,2 ml and HIBOR 3500 IU/0,2 ml (bemiparin sodium) belong to a group of medicines called anticoagulants, which help to prevent your blood from clotting in the blood vessels.

Available in packs of 2, 10, 30 and 100 pre-filled syringes containing 0,2 ml of solution for injection.

HIBOR *must always be prescribed by a doctor and it is used to prevent blood clots, such as in the veins of the legs and/or lungs, which can occur if you are undergoing surgery. It is also used to prevent blood clots forming in the tubing of the dialysis machine.*

BEFORE YOU ARE ADMINISTERED HIBOR

You should not be administered **HIBOR** if:

- If you have had an allergic reaction after being given any medicine containing bemiparin sodium, heparin or substances derived from pigs.
- If you suffer from heparin induced thrombocytopenia (HIT), a condition where there are fewer clotting cells in your blood (platelets) and where laboratory tests show these cells clump together if HIBOR is used. Your doctor will have told you if you have this.
- If you suffer from any condition which results in tendency to bleed excessively.
- If you suffer from a serious liver and/or pancreas disease.
- If you suffer from Disseminated Intravascular Coagulation (DIC) attributable to a heparin-induced decrease in the number of platelets.
- If you suffer from a condition known as endocarditis (an inflammation of the lining of the heart and heart valves). Your doctor will have told you if you have this.

- If you have any lesions with high risk of bleeding (e.g. active stomach ulcer, stroke, brain tumours, or if you have suffered from a brain haemorrhage).
- If you have an injury to or are about to have an operation in the brain, spine, eyes and/or ears.

Take special care:

Check with your doctor, pharmacist or nurse before being administered HIBOR:

- If you suffer from liver or kidney disease.
- If your blood pressure is high and/or difficult to control.
- If you have had a stomach ulcer.
- If you suffer from thrombocytopenia, a condition where there are fewer clotting cells (platelets) in your blood, making you bruise and bleed easily. Your doctor will have told you if you have this.
- If you have stones in the kidney and/or urethra.
- If you suffer from any condition which may cause you to bleed more easily. Ask your doctor if you are unsure.
- If you suffer from eye disorders, attributable to problems in your blood vessels.
- If you are being treated with an anaesthetic injected into your spine (epidural or spinal anaesthesia because of an operation) and/or if you are about to have a lumbar puncture (a puncture in the lower part of your spine for laboratory tests).
- If you suffer from diabetes or have been told that you have high levels of potassium in your blood.
- If your skin turns suddenly blotchy, with bruises and/or red painful blotches. If this happens, tell your doctor immediately.

- **Special advice for use of HIBOR 2500 IU/0,2 ml and HIBOR 3500 IU/0,2 ml:**
    - Children : The use of HIBOR 2500 IU/0,2 ml and HIBOR 3500 IU/0,2 ml is not recommended in children.
    - Elderly: The same dosage should be used for elderly people as for any other adults.
    - Renal and hepatic impairment: There are insufficient data to recommend a dose adjustment of **HIBOR** in this group of patients.

Tell your doctor about other medicines that you are taking as **HIBOR** may interact with these other medicines.

You should read the package insert or patient information leaflet of the other medicines that you will be taking in combination with **HIBOR**.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using HIBOR.

- Pregnancy: Safety in Pregnancy has not been established. **HIBOR** is not recommended for use in pregnant women. Before starting treatment with **HIBOR**, you should notify your doctor if you are or think you could be pregnant. Ask your doctor or pharmacist for advice.

• Breast-feeding: Before starting treatment with **HIBOR**, you should notify your doctor if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery:

HIBOR has no effect on the ability to drive and use precision or dangerous machinery.

Taking other medicines with HIBOR:

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

In particular, do not take this medicine and tell your doctor, if you are taking:

- other anticoagulants, like vitamin K antagonists (warfarin),
- non-steroidal anti-inflammatory drugs like ibuprofen,
- platelet inhibitors like acetyl salicylic acid (aspirin),
- ticlopidine, clopidogrel and other anti-clotting medicines,
- medicines used to prevent the loss of potassium,
- heart drugs like nitroglycerine and medicines to increase your blood volume, like dextran.

Medical tests you may need:

- Some patients may be required to have the level of platelets in their blood checked. Your doctor will decide if this is necessary.
- If you suffer from certain conditions (diabetes, kidney disease) or if you are taking medicines to prevent loss of potassium, your doctor may check the potassium level in your blood.

HOW TO USE HIBOR

You will not be expected to give yourself **HIBOR**. It will be given to you by a person who is qualified to do so. This is because it needs to be given as an injection where the doctor can monitor your progress.

HIBOR MUST NOT BE INJECTED INTO THE MUSCLE NOR MIXED WITH ANY OTHER INJECTION.

TO PREVENT BLOOD CLOTS IN THE VEINS WHEN UNDERGOING SURGERY:

HIBOR 2500 IU IS USUALLY ADMINISTERED BY A DOCTOR OR A NURSE BY SUBCUTANEOUS INJECTION (IT MEANS IS INJECTED UNDER THE SKIN, USUALLY INTO A SKIN FOLD IN YOUR ABDOMEN OR THE UPPER PART OF YOUR THIGH).. YOUR DOCTOR WILL TELL YOU HOW LONG YOU SHOULD BE GIVEN THIS MEDICINE FOR.

If you feel the effect of your medicine is too weak or too strong, tell your doctor, nurse or pharmacist.

If you are not sure why you are receiving **HIBOR** or have any questions about how much **HIBOR** is being given to you, speak to your doctor, pharmacist or nurse.

The correct dose for you will have been decided by the doctor and will depend upon your condition and other existing medical conditions. Your doctor will tell you how long your treatment with **HIBOR** will last.

If you receive more HIBOR than you should:

This may result in bleeding. If this happens, inform your doctor immediately or go to the casualty department at your nearest hospital with this leaflet.

• In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of HIBOR:

DO NOT USE A DOUBLE DOSE TO MAKE UP FOR FORGOTTEN INDIVIDUAL DOSES AND CONSULT YOUR DOCTOR AS SOON AS POSSIBLE SO THAT HE MAY INFORM YOU ON WHAT TO DO IN SUCH AN EVENT.

If you stop having HIBOR:

You should not stop treatment unless your doctor instructs you to.

POSSIBLE SIDE EFFECTS

HIBOR 2500 IU/0,2 ml and HIBOR 3500 IU/0,2 ml can have side effects.

Not all side effects reported for **HIBOR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **HIBOR**, please immediately consult your doctor, pharmacist or other healthcare professional.

Stop using HIBOR and tell a doctor, nurse or pharmacist or go to a hospital straight away if:

BLEEDING OCCURS, WHEN THE NORMAL DOSES ARE GIVEN. IF YOU NOTICE BLOOD IN YOUR URINE OR FAECES OR ANY OTHER TYPE OF BLEEDING TELL YOUR DOCTOR IMMEDIATELY OR GO TO THE CASUALTY DEPARTMENT AT YOUR NEAREST HOSPITAL.

Stop using HIBOR and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Serious allergic reactions may occur (fever, difficulty in breathing, skin itching, redness, sickness, nausea, vomiting). If this happens, stop taking HIBOR 2500 IU/0,2 ml or HIBOR 3500 IU/0,2 ml and consult your doctor immediately or go to the casualty department at your nearest hospital.

If you have been administered anticoagulant drugs and epidural or spinal anaesthesia, bleeding can occur in the spinal area. This may damage the nerves leading to a loss of strength or loss of sensation in your legs or lower body. If this happens, tell a doctor or nurse immediately.

Tell your doctor as soon as possible if you have any of the following side effects:

If you are being treated with HIBOR 2500 IU/0,2 ml or HIBOR 3500 IU/0,2 ml you may develop bruises (violet marks) where you have been injected.

If you are being treated with HIBOR 2500 IU/0,2 ml or HIBOR 3500 IU/0,2 ml (or similar substances) during a long period of time, you could develop osteoporosis, a disease where your bones turn fragile because of a loss of calcium.

Frequently, there is an increase in liver enzymes in your blood (transaminases). There may be a decrease in the number of platelets.

Skin allergic reactions (skin rash, itching) may occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

STORING AND DISPOSING OF HIBOR

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use **Hibor** after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store at or below 25 ºC. Do not freeze**. After first opening, HIBOR should be used immediately.**

PRESENTATION OF HIBOR 2500 IU/0,2 ml and HIBOR 3500 IU/0,2 ml:

0,2 ml of solution in a 0,5 ml pre-filled syringe (transparent, Type I borosilicated glass) with a yellow (2500 IU/0,2 ml) or red (3500 IU/0,2 ml), rubber plunger rod (non-siliconised polypropylene), black, rubber plunger-stopper (Type I chloro butyl rubber) and injection needle (class AISI 304 passivated stainless steel), with a natural rubber tip cap. Packs of 2, 10, 30 and 100 syringes.

INSTRUCTIONS FOR USE/HANDLING:

Single-dose container. Discard any unused content. Do not use if the protective package is opened or damaged. Only clear, colourless or slightly yellowish solutions, free of visible particles, should be used. Any unused product and injection needles should be disposed of in accordance with local requirements.

IDENTIFICATION OF HIBOR

Solution for injection in pre-filled syringes: Colourless, clear or slightly yellowish solution, free from visible particles.

REGISTRATION NUMBER

HIBOR 2500 IE/0,2 ml: A40/8.2/0234

HIBOR 3500 IE/0,2 ml: A40/8.2/0235

NAME AND ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

Zimbili Pharma CC

24 Parrot Avenue,

Extension 1,

Lenasia 1827,

South Africa

DATE OF PUBLICATION

31 October 2017

PROPOSED PATIENT INFORMATION LEAFLET – CLEAN COPY

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME (and dosage form):

HIBOR 5000 IU/0,2 ml (SOLUTION FOR INJECTION)

HIBOR 7500 IU/0,3 ml (SOLUTION FOR INJECTION)

HIBOR 10 000 IU/0,4 ml (SOLUTION FOR INJECTION)

Read all of this leaflet carefully before you are given HIBOR:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or professional healthcare specialist.
- **HIBOR** has been prescribed for you personally and you should not share with other people. It may harm them, even if their symptoms are the same as yours.

WHAT HIBOR CONTAINS:

HIBOR is a solution for injection.

HIBOR 5000 IU/0,2 ml contains: Bemiparin sodium 5000 IU (anti Factor Xa *) per 0,2 ml pre-filled syringe (equivalent to 25 000 IU (anti Factor Xa *) per millilitre of solution for injection).

HIBOR 7500 IU/0,3ml contains: Bemiparin sodium 7500 IU (anti Factor Xa *) per 0,3 ml pre-filled syringe (equivalent to 25 000 IU (anti Factor Xa *) per millilitre of solution for injection).

HIBOR 10 000 IU/0,4 ml contains: Bemiparin sodium 10 000 IU (anti Factor Xa *) per 0,4 ml pre-filled syringe (equivalent to 25 000 IU (anti Factor Xa *) per millilitre of solution for injection).

* Potency is described in International anti Factor Xa activity units (IU) of the 1st International Low Molecular Weight Heparin Reference Standard of the WHO.

It also contains water for injection.

WHAT HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml IS USED FOR:

HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml (bemiparin sodium) belong to a group of medicines called anticoagulants, which help to prevent your blood from clotting in the blood vessels.

Available in packs of 2, 10, 30 and 100 pre-filled syringes containing 0,2 ml, 0,3 ml and 0,4 ml of solution for injection.

HIBOR *must always be prescribed by a doctor and it is used to prevent blood clots, such as in the veins of the legs and/or lungs.*

BEFORE YOU ARE ADMINISTERED HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

You should not be administered **HIBOR** if:

- If you have had an allergic reaction after being given any medicine containing bemiparin sodium, heparin or substances derived from pigs.
- If you suffer from heparin induced thrombocytopenia (HIT), a condition where there are fewer clotting cells in your blood (platelets) and where laboratory tests show these cells clump together if HIBOR is used. Your doctor will have told you if you have this.
- If you suffer from any condition which results in tendency to bleed excessively.
- If you suffer from a serious liver and/or pancreas disease.
- If you suffer from Disseminated Intravascular Coagulation (DIC) attributable to a heparin-induced decrease in the number of platelets.
- If you suffer from a condition known as endocarditis (an inflammation of the lining of the heart and heart valves). Your doctor will have told you if you have this.

- If you have any lesions with high risk of bleeding (e.g. active stomach ulcer, stroke, brain tumours, or if you have suffered from a brain haemorrhage).
- If you have an injury to or are about to have an operation in the brain, spine, eyes and/or ears.

- If you are being treated with HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml or HIBOR 10 000 IU/0,4 ml, epidural or spinal anaesthesia (i.e., during surgery) are contra-indicated.

    - **Take special care when using HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:**

Check with your doctor, pharmacist or nurse before being administered HIBOR:

- If you suffer from liver or kidney disease.
- If your blood pressure is high and/or difficult to control.
- If you have had a stomach ulcer.
- If you suffer from thrombocytopenia, a condition where there are fewer clotting cells (platelets) in your blood, making you bruise and bleed easily. Your doctor will have told you if you have this.
- If you have stones in the kidney and/or urethra.
- If you suffer from any condition which may cause you to bleed more easily. Ask your doctor if you are unsure.
- If you suffer from eye disorders, attributable to problems in your blood vessels.
- If you are being treated with an anaesthetic injected into your spine (epidural or spinal anaesthesia because of an operation) and/or if you are about to have a lumbar puncture (a puncture in the lower part of your spine for laboratory tests).
- If you suffer from diabetes or have been told that you have high levels of potassium in your blood.
- If your skin turns suddenly blotchy, with bruises and/or red painful blotches. If this happens, tell your doctor immediately.

Special advice for use of HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

- Children: The use of **HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml** is not recommended in children.
- Elderly: The same dosage should be used for elderly people as for any other adults.
- Renal and hepatic impairment: There are insufficient data to recommend a dose adjustment of **HIBOR** in this group of patients.

Tell your doctor about other medicines that you are taking as HIBOR may interact with these other medicines.

You should read the package insert or patient information leaflet of the other medicines that you will be taking in combination with HIBOR.

Pregnancy and breast-feeding:

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other health care professional for advice before using this HIBOR.

- Pregnancy:
- Safety in Pregnancy has not been established.
- **HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml** is not recommended for use in pregnant women. Before starting treatment with HIBOR, you should notify your doctor if you are or think you could be pregnant. Ask your doctor or pharmacist for advice.

- Breast-feeding:

  Before starting treatment with **HIBOR**, you should notify your doctor if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery:

HIBOR has no effect on the ability to drive and use precision or dangerous machinery.

Taking other medicines with HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

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

In particular, do not take this medicine and tell your doctor, if you are taking:

- other anticoagulants, like vitamin K antagonists (warfarin),
- non-steroidal anti-inflammatory drugs like ibuprofen,
- platelet inhibitors like acetyl salicylic acid (aspirin),

- ticlopidine, clopidogrel and other anti-clotting medicines,,
- medicines used to prevent the loss of potassium,
- heart drugs like nitroglycerine and medicines to increase your blood volume, like dextran.

Medical tests you may need:

- Some patients may be required to have the level of platelets in their blood checked. Your doctor will decide if this is necessary.
- If you suffer from certain conditions (diabetes, kidney disease) or if you are taking medicines to prevent loss of potassium, your doctor may check the potassium level in your blood.

HOW TO USE HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

You will not be expected to give yourself **HIBOR**. It will be given to you by a person who is qualified to do so. This is because it needs to be given as an injection where the doctor can monitor your progress.

HIBOR MUST NOT BE INJECTED INTO THE MUSCLE NOR MIXED WITH ANY OTHER INJECTION.

Treatment of deep vein thrombosis

Adults: As a general rule, **HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml** is to be administered by subcutaneous injection at the dose of 115 IU/kg/day, once daily, for 7 ± 2 days. This regimen corresponds –depending on the body weight- to the following ranges: < 50 kg, 0,2 ml (5000 IU); 50-70 kg, 0,3 ml (7500 IU), > 70 kg, 0,4 ml (10 000 IU). In patients weighing more than 100 kg body weight, the dose should be adjusted depending on the weight, at a level of 115 IU/kg/day.

Usually you will commence oral anticoagulants 3-5 days after the first administration of **HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml**, and the dose will be adjusted so as to keep a blood test level called the INR value between 2-3 times the control value. Oral anticoagulation is usually continued for at least of 3 months.

If you feel the effect of your medicine is too weak or too strong, tell your doctor, nurse or pharmacist.

If you are not sure why you are receiving **HIBOR** or have any questions about how much **HIBOR** is being given to you, speak to your doctor, pharmacist or nurse.

The correct dose for you will have been decided by the doctor and will depend upon your condition and other existing medical conditions. Your doctor will tell you how long your treatment with **HIBOR** will last.

If you receive more HIBOR than you should:

This may result in bleeding. If this happens, inform your doctor immediately or go to the casualty department at your nearest hospital with this leaflet.

- **In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

If you missed a dose of HIBOR:

DO NOT USE A DOUBLE DOSE TO MAKE UP FOR FORGOTTEN INDIVIDUAL DOSES AND CONSULT YOUR DOCTOR AS SOON AS POSSIBLE SO THAT HE MAY INFORM YOU ON WHAT TO DO IN SUCH AN EVENT.

If you stop having HIBOR:

You should not stop treatment unless your doctor instructs you to.

POSSIBLE SIDE EFFECTS:

HIBOR can have side effects.

NOTE: Not all side effects reported for HIBOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Stop using HIBOR and tell a doctor, nurse or pharmacist or go to a hospital straight away if:

YOU START BLEEDING WHEN THE NORMAL DOSES ARE GIVEN. IF YOU NOTICE BLOOD IN YOUR URINE OR FAECES OR ANY OTHER TYPE OF BLEEDING TELL YOUR DOCTOR IMMEDIATELY OR GO TO THE CASUALTY DEPARTMENT AT YOUR NEAREST HOSPITAL.

Stop using HIBOR and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Serious allergic reactions may occur (fever, difficulty in breathing, skin itching, redness, sickness, nausea, vomiting). If this happens, stop taking HIBOR and consult your doctor immediately or go to the casualty department at your nearest hospital.

If you have been administered anticoagulant drugs and epidural or spinal anaesthesia, bleeding can occur in the spinal area. This may damage the nerves leading to a loss of strength or loss of sensation in your legs or lower body. If this happens, tell a doctor or nurse immediately.

Tell your doctor as soon as possible if you have any of the following side effects:

If you are being treated with HIBOR you may develop bruises (violet marks) where you have been injected.

If you are being treated with HIBOR (or similar substances) during a long period of time, you could develop osteoporosis, a disease where your bones turn fragile because of a loss of calcium.

Frequently, there is an increase in liver enzymes in your blood (transaminases). There may be a decrease in the number of platelets.

Skin allergic reactions (skin rash, itching) may occur.

NOTE: Not all side effects reported for HIBOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

STORING AND DISPOSING OF HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

Store at or below 25°C. Do not freeze. After first opening, HIBOR should be used immediately.

Unused or expired medicines can be disposed of by your nearest pharmacy.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

PRESENTATION OF HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

0,2 ml, 0,3 ml and 0,4 ml of solution in a 0,5 ml pre-filled syringe (transparent, Type I borosilicated glass) with a natural, rubber plunger rod (non-siliconised polypropylene), black, rubber plunger-stopper (Type I chloro butyl rubber) and injection needle (class AISI 304 passivated stainless steel), with a natural rubber tip cap. Packs of 2, 10, 30 and 100 syringes.

INSTRUCTIONS FOR USE/HANDLING:

Single-dose container. Discard any unused content. Do not use if the protective package is opened or damaged. Only clear, colourless or slightly yellowish solutions, free of visible particles, should be used. Any unused product and injection needles should be disposed of in accordance with local requirements.

IDENTIFICATION OF HIBOR 5000 IU/0,2 ml, HIBOR 7500 IU/0,3 ml and HIBOR 10 000 IU/0,4 ml:

Solution for injection in pre-filled syringes: Colourless, clear or slightly yellowish solution, free from visible particles.

REGISTRATION NUMBER / REFERENCE NUMBER:

Pre-filled syringes:

HIBOR 5000 IU/0,2 ml: A40/8.2/0236

HIBOR 7500 IU/0,3 ml: A40/8.2/0237

HIBOR 10 000 IU/0,4 ml: A40/8.2/0238

NAME, ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE REGISTRATION CERTIFICATE:

Zimbili Pharma CC

24 Parrot Avenue,

Extension 1,

Lenasia 1827,

South Africa

DATE OF PUBLICATION:

31 October 2017.