Patient Information Leaflet

SCHEDULING STATUS: S4

BEDORAL® 30 Solution for injection

Ketorolac Tromethamine

Sugar free Remains unchanged

Read all of this leaflet carefully before you are given BEDORAL® 30

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

What is in this leaflet

1. WHAT BEDORAL® 30 IS AND WHAT IT IS USED FOR

BEDORAL ® 30 is a non-steroidal anti-inflammatory agent used in the short term management of moderate pain relief after operations. It also has some properties to reduces redness, swelling and fever. **BEDORAL ® 30** should only be administered by or under the supervision of your doctor.

2. What you need to know before you take BEDORAL® 30

BEDORAL® 30 should not be administered to you

- If you are hypersensitive to the active ingredient Ketorolac Tromethamine or other NSAIDS.
- If taking aspirin brings about an allergic reaction.

- If you have internal bleeding of the stomach or intestines.
- if you have stomach or duodenal ulcers, or bleeding of those ulcers.
- If you suffer from bleeding or clotting of blood disorders.
- If you are on medication to thin the blood or to prevent the clotting of blood.
- If you have reduced kidney function or if you are at risk of kidney failure.
- If you are pregnant or breastfeeding.
- If you are below the age of 16.
- If you are taking medication containing oxypentifylline.
- If you are pregnant, do not use **BEDORAL ® 30** at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because these medicines may cause harm in your unborn baby.
- Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/ taking/ using **BEDORAL® 30**, as **BEDORAL® 30** can sometimes worsen wound healing in your gut after surgery.

Warnings and precautions

Tell your doctor of health care provider before being given the injection:

- If you have internal bleeding of the stomach or intestines.
- if you have stomach or duodenal ulcers, or bleeding of those ulcers.
- If you have reduced kidney function or if you are at risk of kidney failure.
- If you asthma or difficulty breathing.
- If you chronic pain, as **BEDORAL ® 30** is not indicated for chronic pain.
- If you have high blood pressure, swelling due to retention of fluid or any heart problems.
- If you have any liver abnormalities.
- If you are pregnant, do not use **BEDORAL ® 30** at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid

that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.

- Additionally do not use **BEDORAL ® 30** at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.
- If you develop a skin rash, fever, swelling of lymph nodes and and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Children and adolescents

BEDORAL® 30 injection is not recommended for use in children under 16 years of age.

Other medicines and BEDORAL® 30

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

The use of **BEDORAL ® 30** with certain medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Care is needed if you are taking:

- NSAIDS (used for pain relief)
- Oxypentifylline (used to treat muscle pain)
- Methotrexate (used as in immune suppressant)
- ACE inhibitors (used to treat hypertension i.e blood pressure)
- Lithium containing drugs (used to treat psychiatric disorders)
- Salicylates (example Aspirin)
- Anticoagulants (used to prevent blood clotting)
- Furosemide (water pills)

Pregnancy, breast-feeding and fertility:

Pregnancy

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BEDORAL ® 30**.

Do not use **BEDORAL ® 30** at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because this medicine may cause kidney problems in the unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles to develop. Complications can occur with low levels of this fluid.

Additionally do not use **BEDORAL ® 30** at 30 weeks or later in pregnancy since it can cause a passage in the baby's heart to close prematurely, possibly leading to heart or lung damage, or even death.

Breast-feeding

You should not use **BEDORAL ® 30** if you are breastfeeding.

Driving and using machinery:

The use of **BEDORAL ® 30** may cause drowsiness, vertigo, dizziness, insomnia, or depression. If you experience any of them caution should be exercised in carrying out activities that require alertness.

3. HOW TO TAKE BEDORAL ® 30

Do not share medicines prescribed for you with any other person.

Always take **BEDORAL ® 30** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of **BEDORAL ® 30** will be decided by your doctor based on your condition. You will not be expected to give yourself **BEDORAL ® 30. BEDORAL ® 30** is administered by injection into a muscle (intramuscularly) or into a vein (intravenously) by a doctor or under his or her supervision.

BEDORAL ® 30 injection may be used for short-term use, not exceeding 24 hours. **BEDORAL ® 30** is not recommended for use in children below the age of 16.

If you take more BEDORAL ® 30 than you should

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

Since a health care provider will administer **BEDORAL ® 30**, he/she will control the dosage.

If you forget to take BEDORAL ® 30

Since a health care provider will administer **BEDORAL ® 30,** it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

BEDORAL ® 30 can have side effects.

Not all side effects reported for **BEDORAL ® 30** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BEDORAL ® 30**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **BEDORAL ® 30** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Small purple coloured spots caused by bleeding into the skin.
- Convulsions.
- Yellowing of skin and eyes, also called jaundice.

- Allergic skin reaction and itching.
- Injection site reaction
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **BEDORAL ® 30.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pains
- Abnormally slow pulse rate
- Rapid irregular action of the heart
- Unhealthy pale appearance
- Rapid reddening of the skin
- Difficulty in breathing
- Less urine than is normal for you

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Headache
- Dizziness
- High pressure
- Nausea
- Heartburn

- Stomach cramps and discomfort
- Vomiting
- Increased or decreased frequency of stools
- Excessive thirst
- Discomfort to stomach

Less frequent side effects:

- Nose bleeds
- Feeling depressed and having false perceptions
- Hearing difficulties
- Low blood pressure
- Bleeding ofduodenal ulcers

Frequency unknown side effects:

- Difficulty sleeping
- Dry mouth

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effect you can help provide more information on the safety of **BEDORAL ® 30**.

5. HOW TO STORE BEDORAL ® 30

Store all medicines out of reach of children.

- Store at or below 25 ^{0}C
- Store in the original package / container
- Protect from light
- Do not use after the expiry date stated on the label / carton / ampoule
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BEDORAL ® 30 contains

The active substance is Ketorolac Tromethamine.

Each 1 ml ampoule of **BEDORAL ® 30** contains 30 mg of ketorolac tromethamine

The other ingredients are disodium edetate, potassium dihydrogen phosphate, propylene glycol, sodium chloride, sodium hydroxide and water for injection.

What BEDORAL ® 30 looks like and contents of the pack

BEDORAL ® 30 is a clear, colourless solution, free from visible particles and fibres.

BEDORAL ® 30 is packed in a 2 ml clear USP type-1 glass ampoules each containing 1 ml solution.

Ampoules are supplied in cartons of 10 ampoules.

Holder of Certificate of Registration and Manufacturer

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