SCHEDULING STATUS **S3**

BETACIN 25 mg Capsules

Indomethacin

Contains Sugar: Lactose 86,83 mg per capsule

Read all of this leaflet carefully before you start taking BETACIN®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- BETACIN®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 BETACIN® is and what it is used for
2. What you need to know before you take BETACIN®
3. How to take BETACIN®
4. Possible side effects
5. How to store BETACIN®
6. Contents of the pack and other information

1. What is and what it is used for

BETACIN® contains indomethacin which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Indomethacin contains properties for the management of pain, inflammation and fever.

BETACIN® are used for the treatment of:

- Inflammatory disease of the joints (rheumatoid arthritis)
- wear and tear of joints (osteo-arthritis)
- progressive stiffening of the spine (ankylosing spondylitis)
- injuries or pain in the human musculoskeletal system, including the joints, ligaments, muscles, nerves, tendons, and the structures that support the limbs, neck and back. (acute musculoskeletal disorders)
- Arthritis caused by the formation of uric acid crystals in the joints. (Gout

2. What you need to know before you take BETACIN®

Do not take BETACIN®

- If you are hypersensitive (allergic) to indomethacin or any of the other ingredients of BETACIN® (see section 6).
- If you previously shown sensitivity to indomethacin or to asprin
- If you operating machinery, or patients with psychiatric disorders, epilepsy or parkinsonism
- If you have renal disease or ulcerative lesions of the stomach or intestines.
- If you have bleeding disorders, active peptic ulcers, gastritis, regional enteritis and ulcerative colitis
- Pregnant and nursing women and in children.

- If you have heart failure**.**
- If you have a history of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs
- If you have active or history of recurrent ulcer/haemorrhage/perforations.

Warnings and precautions

Take special care with BETACIN® if you:

- have diabetes
- suffer from internal bleeding of the stomach or intestines
- suffer from stomach ulcers
- suffer from high blood pressure or any other heart diseases
- are unable to take aspirin or any other NSAIDS
- are on medication that prevents blood clotting
- suffer from a blood platelet condition
- have been taking BETACIN® for prolonged period of time or if you suddenly stop taking these tablets
- suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)
- are a female trying to have a baby or have any history of fertility problems
- If you develop a skin rash fever, swelling of lymphnodes and and an increase of eosinophils (a typeof white blood cells). This is known as Drug Reaction with Eosinophilia and SystemicSymptoms (DRESS).

Other medicines and BETACIN®

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently using:

- Other analgesics (medicines for pain or fever)
- Antacids (medicines for indigestion or heartburn)
- anti-coagulants (medicines that prevent blood clotting)
- anti-depressants (medicines to treat mood disorders)
- anti-diabetic (medicines used to treat diabetes
- antihypertensive(medicines used to treat high blood pressure)
- anti-platelets (medicines that prevent blood platelets from sticking together and forming clots)
- antivirals (medicines used to treat viral infections)
- Antisychotic medication
- corticosteroids
- aspirin or any other Non-steroidal anti-inflammatory drugs (NSAIDs)
- Diuretics (water medication)
- heart medication
- ciclosporin (used to prevent organ rejection after a transplant)
- Corticosteroids
- Cytotoxic
- Desmopressin
- Diflunisal
- Lithium
- Methotrexate

- Mifepristone
- Muscle Relaxants
- Pentoxifylline
- Probenecid
- Quinolone antibiotics
- Salicylates
- Tacrolimus
- Tiludronic acid
- Triamterene

BETACIN® with food, drink and alcohol

BETACIN® is given with food, milk or an antacid

Bioavailability may be reduced with antacids containing aluminium hydroxide, magnesium carbonate and magnesium hydroxide.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BETACIN®

Driving and using machines

The use of BETACIN® may cause dizziness, light-headedness, drowsiness, fatigue, visual disturbances or imbalance. If you experience any of them, caution should be exercised in carrying out activities that require alertness and one should not drive or operate machinery

BETACIN® contains Lactose

BETACIN® contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take BETACIN®.

3. How to take BETACIN®

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

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

The recommended dosage is 25mg to 200mg daily divided in two to four equal doses, given with food, milk or an antacid. Therapy may be initiated with low doses and gradually increasing them where necessary according to the patients response and requirements. Bioavailability may be reduced with antacids containing aluminium hydroxide, magnesium carbonate and magnesium hydroxide.

Use the lowest effective dose for the shortest possible duration of treatment.

Your doctor will tell you how long your treatment with BETACIN® will last. Do not stop treatment early because you feel better. If you have the impression that the effect of BETACIN® is too strong or too weak, tell your doctor or pharmacist.

If you take more BETACIN® CAPSULES than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

If you forget to take BETACIN®:

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose to make up for forgotten individual doses. You should contact your doctor on how to proceed

4. Possible side effects

BETACIN® can have side effects.

Not all side effects reported for BETACIN® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this BETACIN®, please consult your health care provider for advice.

If any of the following happens, stop taking

BETACIN ® capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **signs of bleeding in the stomach:**

- Pass blood in your faeces (stools/motions)

- Pass black tarry stools

- Vomit any blood or dark particles that look like

coffee grounds

• **signs of an allergic reaction:**

- difficulty breathing or swallowing, asthma,

sudden decrease in blood pressure

- swelling of the face, lips, tongue or throat.

- 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 all very serious side effects. If you have them, 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:

• **abdominal pain** (pains in your stomach) or other abnormal stomach symptoms

• **effects on the stomach** such as feeling or being sick, inflammation of the stomach lining, small intestine or mouth, constipation, diarrhoea, wind, perforation of previous intestinal damage, narrowing of or blockage in the intestine

• **abnormal liver function** (as seen in blood tests)

• **liver disease**: yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis),causing fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever

• **skin reactions** such as itching, pale or red irregular raised patches with severe itching (hives), disorder characterised by blood spots, bruising and discolouring of the skin (purpura), blisters or skin that is red, flaky or peeling such as severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), circular, irregular red patches on the skin of the hands and arms (erythema multiforme),severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome)

• **aseptic meningitis** (stiff neck, headache, feeling or being sick, fever, disorientation) especially in those who already have an auto-immune disease such as systemic lupus erythematosus or mixed connective tissue disease.

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

Tell your doctor if you notice any of the following:

• **Eyes:**

- blurred and double vision
- inflammation of the optic nerve (which may cause eye pain and loss of vision)
- eye pain
- changes in your sight.

• **Ear:**

- ringing or buzzing in the ears
- hearing disturbances including deafness.

• **Blood:**

- small purple red spots, nosebleeds, bruising,

disorder characterised by blood spots, blood clotting throughout the body, disturbance of blood count, reduction in blood cell production by the bone marrow. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.

• **Metabolism:**

- high blood sugar
- sugar in the urine

- high blood levels of potassium (muscle cramps or pain, irregular heartbeat, unusual tiredness or weakness).

• **Nervous system:**

- headache, dizziness, lightheadedness, spinning sensation (vertigo), tiredness, fainting, a feeling of general discomfort and illness, drowsiness, coma, fluid in the brain causing swelling
- depression, nervousness, confusion, hallucinations, anxiety and other mental health problems, a feeling of unreality (that the mind is separated from the body), difficulty sleeping speech disorder, fits or seizures, worsening of epilepsy, disorder of the nerves causing tingling and numbness, pins and needles
- uncontrolled movements, worsening of parkinsonism (tremor, stiffness and shuffling).

• **Heart:**

- fluid retention causing swelling, chest pain, heart failure (symptoms include shortness of breath, tiredness, increased heart rate, flushing, swelling - especially of the ankles)
- high and low blood pressure (symptoms include

dizziness, fainting, light-headedness, nausea,heart attack)

- racing heartbeat, irregular heartbeat, palpitations.

• **Blood vessels:**

- flushing.

• **Breathing:**

- increase in the number of white blood cells in the lungs
- narrowing of the airways in those who have a history of asthma or allergic disease.

Stomach and intestines:

- loss of appetite

- development or worsening of ulcerative colitis or Crohn's disease

- inflammation of the pancreas causing pain and tenderness in the abdomen and back (pancreatitis)**.**

• Skin:

- inflammation of blood vessels

- sensitivity to sunlight or artificial light (e.g. sunbeds)

- tender red lumps usually on the legs (erythema nodosum)

- hair loss, sweating

- worsening of psoriasis (itchy scaly pink patches on the elbows, knees, scalp and other parts of the body).

• Liver:

- blocked bile flow (pale coloured stools, dark urine, itching).

• Muscle and bone:

- muscle weakness, increased breakdown of cartilage.

• Kidneys:

- blood in the urine

- nephrotic syndrome (increased protein in urine and fluid retention)

- too much protein in the urine

- inflammation of the kidneys, reduced kidney function or kidney failure.

• Reproductive system:

- bleeding from the vagina

- breast enlargement or tenderness, enlarged breasts in men.

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 **BETACIN®**.

5. How to store BETACIN®,

- 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
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BETACIN®, contains

Each capsule contains 25 mg indomethacin.

The other ingredients are: magnesium stearate, microcrystalline cellulose (avicel ph 101), purified talc, sodium lauryl sulphate, sodium starch glycolate (explotab), starch maize (dried), tablettose (lactose)

Hard Gelatine Capsule

Quinoline yellow WS (C.I. 47005), sunset yellow FCF (C.I. 15985), titanium dioxide (Cl 77891)

Red Marking Solution RDL001

Butyl alcohol, dehydrated alcohol, isopropyl alcohol, polysorbate 80, poncrea 4R lake, propylene glycol,

shellac, strong ammonia solution, titanium dioxide

Black Marking Solution BKI001

Black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, propylene glycol, shellac

What BETACIN®, looks like and the contents of the pack

A size 3 yellow gelatine capsule imprinted with **Betacin®** on the cap in red colour and black colour on the body, containing a white to off-white powder.

Bottles of 100, 500, 1000 capsules.

Patient ready packs of different pack sizes.

Holder of Certificate of Registration

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