SCHEDULING STATUS

S3

INNOFLAM 100 mg capsules, hard

INNOFLAM 200 mg capsules, hard

Celecoxib

Contains sugar: Lactose monohydrate.

Each **INNOFLAM** 100 capsule contains 25 mg of lactose monohydrate.

Each **INNOFLAM** 200 capsule contains 50 mg of lactose monohydrate.

Read all this leaflet carefully before you start taking INNOFLAM

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- **INNOFLAM** 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

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2. What you need to know before you take **INNOFLAM**

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1. What INNOFLAM is and what it is used for

INNOFLAM belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), and specifically a sub-group known as cyclooxygenase-2 (COX-2) inhibitors.

Your body makes substances called prostaglandins. Some prostaglandins may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. **INNOFLAM** acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

INNOFLAM is used in adults for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis (progressive stiffening of the spine).

INNOFLAM is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, primary dysmenorrhoea (painful menstrual periods).

2. What you need to know before you take INNOFLAM

Do not take INNOFLAM:

- if you are hypersensitive (allergic) to celecoxib or any of the ingredients of **INNOFLAM** (see section 6 “What this product contains”);
- if you have had an allergic reaction to a group of medicines called “sulphonamides” (medicines that prevent the growth of bacteria)
- if you have severe liver disease**;**
- if you have severe kidney disease;
- if you have had allergic reactions such as asthma, nose polyps, severe nasal congestion, or an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or

wheezing from aspirin or other NSAIDs (anti-inflammatory and pain-relieving medicines, such as diclofenac, ibuprofen).

- Established ischaemic heart disease, or cerebrovascular disease, e.g. you have been diagnosed with a heart attack, stroke, or blockages of blood vessels to the heart or brain;

- if you are about to have coronary artery bypass graft surgery;
- if you currently have an ulcer in your stomach or intestines, or if you are bleeding in your stomach or intestines (you may notice that you have black sticky stools or bloody diarrhoea);
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease
- if you are pregnant or it is possible that you could become pregnant;
- if you are breastfeeding.

Talk to your doctor or pharmacist before taking **INNOFLAM**:

Take special care with **INNOFLAM**:

- if you smoke, have diabetes, high blood pressure or high blood cholesterol;
- if you have had a serious allergic reaction or a serious skin reaction to any medicines;
- if you have previously had an ulcer or bleeding in your stomach or intestines. (**Do not take INNOFLAM** if you currently have an ulcer or bleeding in your stomach or intestine);
- if you are taking corticosteroid medicines (for example prednisone);
- if you are taking aspirin (even at low dose for heart protective purposes);
- if you use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban).

- if you are taking **INNOFLAM** at the same time as other non-aspirin NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided;
- if you have fluid retention (such as swollen ankles and feet);
- if you have heart failure or other heart problems;
- if you have high blood pressure;
- if your liver or kidneys are not working well, as your doctor may want to keep a regular check on you;
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (medicines used to get rid of excess fluid in the body);
- if you feel ill due to an infection, or think you have an infection, as **INNOFLAM** may mask a fever or other signs of infection and inflammation.
- If you are above 65 years of age your doctor will want to monitor you regularly.

The consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems.

INNOFLAM may lead to an increase in blood pressure. Your doctor may want to monitor your blood pressure on a regular basis.

Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.

Other medicines and INNOFLAM

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

Before you take **INNOFLAM**, make sure your doctor knows if you are taking the following medicines:

- Warfarin (used to prevent blood from clotting)
- ACE inhibitors, angiotensin II receptor antagonists, beta blockers (used for high blood pressure and heart failure)
- Diuretics (used to treat fluid retention)
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants).
- Aspirin (used for pain and fever). **INNOFLAM** can be taken with low dose aspirin (75 mg or less daily). Ask your doctor for advice before taking both medicines together

  INNOFLAM has no antiplatelet effect and is therefore not a substitute for aspirin for prevention of thrombosis
- Neuroleptics (used to treat some mental disorders)
- Medicines for anxiety (diazepam) or to treat depression (citalopram, imipramine)
- Medicines to treat an irregular heartbeat (amiodarone, quinidine)
- Dextromethorphan (used to treat coughs)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Lithium (used to treat some types of depression)
- Oral contraceptives
- Glibenclamide, tolbutamide (medicines used in the management of type 2 diabetes)
- Phenytoin, a medicine used in epilepsy (seizure disorder)
- Fluconazole (used to treat fungal infection)
- Rifampicin (used to treat bacterial infections)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)

- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Ketoconazole (an antifungal medicine)
- Antacids (used for heartburn).

Pregnancy, breastfeeding 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 healthcare provider for advice before taking **INNOFLAM**.

Pregnancy

INNOFLAM must not be used by women who are pregnant or can become pregnant (i.e. women of childbearing potential who are not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with **INNOFLAM** you should discontinue the treatment and contact your doctor for alternative treatment.

Breastfeeding

INNOFLAM must not be used during breastfeeding.

Fertility

NSAIDs, including **INNOFLAM**, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

You should be aware of how you react to **INNOFLAM** before you drive or operate machinery. If you feel dizzy or drowsy after taking **INNOFLAM**, do not drive or operate machinery until these effects wear off.

INNOFLAM contains lactose

INNOFLAM contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **INNOFLAM**.

3. How to take INNOFLAM

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

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

If you think or feel that the effect of **INNOFLAM** is too strong or too weak, talk to your doctor or pharmacist.

Use the lowest effective dose for the shortest possible time.

Your doctor will tell you what dose you should take.

The recommended dose for osteoarthritis is 200 mg taken as a single dose, or as two divided doses.

The recommended dose for rheumatoid arthritis is 100 mg or 200 mg twice daily.

The recommended dose for pain following dental surgery is 100 mg or 200 mg twice daily.

The recommended dose for pain following an operation is 200 mg once daily.

The recommended dose for musculoskeletal pain is 200 mg twice daily.

The recommended dose for primary dysmenorrhoea is 400 mg initially, followed by an additional 200 mg on the first day if needed. On subsequent days, the recommended dose is 200 mg twice daily.

The recommended dose for ankylosing spondylitis is 200 mg daily, taken as a single dose or as 100 mg twice daily.

If you have liver problems, or if you weigh less than 50 kg, your doctor will recommend the

lowest recommended dose.

Children:

No information is available on the use of **INNOFLAM** in children and it is therefore not recommended for use in children.

Method of administration:

INNOFLAM is for oral use. Swallow the capsules whole with a glass of water at any time of the day, with or without food. However, try to take each dose of **INNOFLAM** at the same time each day. Do not chew or crush the granules.

Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

If you take more INNOFLAM than you should

You should not take more capsules than your doctor tells you to.

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

If you forget to take INNOFLAM

If you forget to take a capsule, take it as soon as you remember.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking INNOFLAM

Suddenly stopping your treatment with **INNOFLAM** may lead to your symptoms getting worse. Do not stop taking **INNOFLAM** unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

INNOFLAM can have side effects.

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

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

- swelling of the hands, feet ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- a serious skin reaction with rash, blistering or peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to **INNOFLAM**. 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

- weakness or clumsiness of a hand, arm or leg, difficulties with speech and swallowing, vision problems and headache. These may be signs of a stroke or bleeding in the brain, which may be fatal
- shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm (heart attack)
- problems breathing, shortness of breath, chest pain. You may have a blood clot in the lung (pulmonary embolism) and will need urgent medical attention
- throbbing or cramping pain in a leg, swelling in a leg, warm skin around painful area (deep vein thrombosis)

- severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood
- liver failure (symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow))
- bladder or kidney infections. Some signs may be fever, chills, blood in the urine or frequent urination
- acute renal failure/nephrotic syndrome (decreased urine output, swelling of legs, fatigue, foamy urine, loss of appetite)
- painful blisters, sensitive to touch (shingles)
- red, swollen, painful skin with fever (a bacterial skin infection, known as erysipelas)
- ache or burning pain in your abdomen (Helicobacter infection).

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- infections of the airways such as sinusitis (swelling and redness of the nasal sinuses) or bronchitis (inflammation of the mucous membranes of the airways)
- worsening of existing allergies
- weight gain
- trouble sleeping
- dizziness, abnormal muscle tension
- headache
- high blood pressure, worsening of existing high blood pressure. you may not know that you have high blood pressure unless you have your blood pressure tested.

- runny nose, sore throat, shortness of breath.
- nausea (feeling sick), vomiting (being sick)
- indigestion, windiness, pain on stomach
- problem swallowing
- sore teeth
- skin rash, itching skin.
- accidental injury.
- flu-like illness
- keeping fluid back in the body tissues, with swollen ankles, legs and/or hands.

<u>Less frequent side effects</u>

- inflammation or infection of the inner ear (dizziness or feeling that everything is spinning around you)
- infection of the gums
- blood disorders, such as anaemia (too few red blood cells or their haemoglobin content is too low), leukopenia (a lowered white blood cell count) or thrombocytopenia (deficiency of platelets in the blood)*

  * You will only know that you have these disorders if your doctor orders blood tests. See your doctor if you are pale and tired, get more infections than usual or have problems to stop bleeding, or if you have unexpected bruising
- increased sodium in blood, increased potassium in blood (determined by blood tests)
- feeling tired, confused
- feeling anxious or depressed
- seeing or hearing things that do not exist (hallucinations)

- blurred vision, eye inflammation and bloodshot eyes, vitreous floaters (seeing spots or strings that move when you move your eyes), bleeding in an eye, painful eyes
- ringing in the ears, above normal hearing sense, voice disorder
- irregular heart rhythm, increased heart rate
- flushing
- inflammation of a blood vessel (you may feel unwell with fever, sweats and tiredness)
- tightness in the chest with coughing and wheezing (bronchospasm)
- shortness of breath, cough, fatigue (inflammation of the lung tissues - pneumonitis)
- abdominal pain, cramping, bloating, constipation
- mouth ulcers, numbness, burning sensation in the mouth (stomatitis)
- hair loss
- muscle spasms (leg cramps), muscle pain
- lower limb fracture
- kidney function disorders (shown by laboratory tests)
- frequent urination during the night (nocturia)
- menstrual disorders
- swollen face
- chest pain.

<u>Frequency unknown</u>

- sleepiness
- abnormal skin sensations (tingling or tickling or itching or burning)

- problems with coordination and speech (ataxia)
- no sense of smell or taste, or taste affected
- worsening of existing epilepsy (seizure disorder)
- female fertility decreased
- vaginal bleeding
- tender breasts.

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, pharmacist or nurse. 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 effects, you can help provide more information on the safety of **INNOFLAM**

5. How to store INNOFLAM

- Keep out of reach and sight of children.
- Store at or below 30 °C in the original carton until removed for use.
- Protect from moisture.
- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What INNOFLAM contains

The active substance is celecoxib.

1 capsule contains 100 mg or 200 mg celecoxib.

The other ingredients are: croscarmellose sodium, FD & C blue # 2 aluminium lake, gelatin, lactose monohydrate, magnesium stearate, povidone, purified water, shellac, sodium lauryl sulfate, titanium dioxide E 171, yellow iron oxide.

What INNOFLAM looks like and contents of the pack

INNOFLAM 100: Hard gelatin capsules size “3” having imprinting “135” on the opaque white body with blue ink and “A” on the opaque white cap with blue ink filled with white to off white colored granular powder.

INNOFLAM 200: Hard gelatin capsules size “1” having imprinting “136” on the opaque white body with golden yellow ink and “A” on the opaque white cap with golden yellow ink filled with white to off white colored granular powder.

INNOFLAM 100 & 200 are available in:

- (10’s, 20, 30’s & 60’s) blisters of unprinted aluminum foil & unprinted CFB foil in one carton. In pack sizes of multiples of 10 capsules per blister.
- (10’s, 20’s,30’s &60’s) blisters of plain aluminum foil & plain OPA/ALU/PVC CFB foil in one carton. In pack sizes of multiples of 10 capsules per blister.
- (10’s, 20’s, 30’s & 60’s) blisters of plain aluminum foil & transparent PVC/PE/PVDC film in one carton. In pack sizes of multiples of 10 capsules per blister.

Holder of Certificate of Registration

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