PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MELZY 7,5 / 15 tablets

Meloxicam

Contains sugar: Lactose monohydrate.

MELZY 7,5 contains 30,25 mg and MELZY 15 contains 60,50 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking MELZY

- 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.
- MELZY 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 MELZY is and what it is used for
2. What you need to know before you take MELZY
3. How to take MELZY
4. Possible side effects
5. How to store MELZY
6. Contents of the pack and other information.

1. What MELZY is and what it is used for

MELZY contains the active ingredient meloxicam, which belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs are used to reduce inflammation and

pain in joints and muscles.

MELZY is used for the symptomatic treatment of:

- Rheumatoid arthritis (an autoimmune and inflammatory disease that may cause joint pain, inflammation, and damage throughout your body).
- Painful osteoarthritis (degenerative joint disease, causing pain and stiffness of your joints).
- Ankylosing spondylitis (type of arthritis that mainly affects your back, by causing inflammation and progressive stiffening of your spine).
- Episodes of acute sciatica (pain caused by irritation of the sciatic/hip nerve, which branches from your lower back through your hips and buttocks down each leg).

2. What you need to know before you take MELZY

Do not take MELZY:

- If you are hypersensitive (allergic) to meloxicam or any of the other ingredients of MELZY (listed in section 6).
- If you previously suffered from any of the following after taking aspirin or any other pain medication:
    - Asthma (wheezing, chest tightness, breathlessness).
    - Skin hives (skin rash/raised red patches on your skin with severe itching).
    - Nasal polyps (nasal blockage due to swellings in the lining of your nose).
    - Angioedema (painless swelling under your skin).
    - Acute rhinitis (runny nose).
- If you have recently undergone heart surgery (for narrowed or blocked arteries), since MELZY should not be used to treat pain after such an operation.
- If you have, or have had a recurring ulcer/sore in your stomach or intestines, or perforation or bleeding.
- If you have been diagnosed with Crohn’s disease or ulcerative colitis (an inflammatory bowel disease with symptoms such as abdominal pain and cramping, bloody diarrhoea, rectal pain

or bleeding, weight loss and fatigue).

- If you suffer from severe liver disease.
- If you suffer from severe kidney disease and are not undergoing dialysis.
- If you suffer from any kind of established bleeding disorder, bleeding in your stomach or intestines, or recent cerebrovascular bleeding (bleeding in your brain).
- If you have a heart condition such as heart failure or ischaemic heart disease (not enough blood flowing to/from your heart with symptoms such as shortness of breath, fatigue and swelling in your legs, ankles and feet) and/or a condition that affects the blood vessels and blood supply to your brain (stroke) or peripheral arterial disease (a condition in which narrowed arteries reduce blood flow to your arms or legs).
- If you have ever suffered from gastrointestinal bleeding (bleeding in your stomach or intestines), ulceration or perforation after taking aspirin or any other anti-inflammatory medicines, including MELZY.
- If you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).
- If you or your child are younger than 12 years of age.
- If you have been told by your doctor that you have an intolerance to some sugars, as MELZY contains lactose monohydrate (see **MELZY contains lactose monohydrate**).

Warnings and precautions

Take special care with MELZY:

MELZY may cause you to have heart and/or blood vessel problems, stomach and/or intestine problems, or skin reactions which may be fatal.

- Do not exceed the maximum recommended daily dose or take additional anti-inflammatory medicines with MELZY if the therapy is not sufficient, as it may cause an increased risk of bleeding/ulcers.

- Consult your doctor if you don't have improvement of your symptoms after several days.
- If you are an elderly patient, you may be more likely to experience the side effects of MELZY, especially bleeding in your stomach and intestines, ulceration or perforation (which may be fatal).
- If you have a history of oesophagitis (inflammation of your oesophagus with symptoms such as painful swallowing, heartburn, nausea, vomiting), gastritis (inflammation of the lining of your stomach) and/or stomach ulcer, tell your doctor before starting treatment with MELZY.
- If you need to take higher anti-inflammatory doses or if you are an elderly patient, your doctor may prescribe the lowest dose of MELZY as well as an additional medicine to reduce the amount of acid produced in your stomach or to protect the lining of your stomach. Should the symptoms of either stomach ulcer or bleeding occur, stop taking MELZY immediately and consult your doctor.
- MELZY may be associated with an increased risk of heart problems with higher doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- If you have any risk factors such as high blood pressure, increased cholesterol levels, diabetes (increased blood sugar levels) or if you are a smoker, as these may increase your risk of a heart attack or stroke.
- If you have any heart problems or any other conditions that may be worsened by fluid retention (excessive build-up of fluid in the body), such as high blood pressure, as MEZLY may cause fluid retention and worsen these conditions.
- If you notice any skin rash, sores in the lining of your nose or mouth, swollen glands, fever or any other signs of allergy, you must stop taking MELZY immediately, since it can be the first signs of a very serious skin reaction.
- If you suffer from any kidney or liver problems.
- Your kidney function should be carefully monitored if you have any of the following risk factors:
    - You are an elderly patient.
    - Are dehydrated.

- Taking medicines to treat high blood pressure such as water tablets.
- Hypovolaemia (a condition that occurs when your body loses fluid, like blood or water).
- You have a kidney disease or kidney failure.

- If you have been diagnosed with high sodium or potassium levels in the blood, or if you are retaining water (swollen hands or feet). If you are diabetic, your potassium levels should be monitored regularly.
- MELZY may hide the symptoms of an infection (e.g. fever).
- Do not use MELZY as a substitute for aspirin as a preventative treatment for cardiovascular disease (conditions affecting your heart or blood vessels).
- Use the lowest effective dose for the shortest period necessary to control symptoms, as this may help to reduce side effects.

Children and adolescents

MELZY should not be used in children below 12 years of age as the safety and efficacy have not been established.

Other medicines and MELZY

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

Tell your doctor if you are taking/using or have taken any of the following:

- Antiplatelet medicines, including aspirin (used to thin your blood), and other nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat inflammation and pain).
- Corticosteroids such as glucocorticoids (used to treat various inflammatory or skin conditions).
- Anticoagulants (such as warfarin and heparin) or thrombolytics (used to thin your blood or break down blood clots).
- Selective serotonin reuptake inhibitors (SSRIs) (used in the treatment of depression).

- Antihypertensive medicines (used to treat high blood pressure), such as diuretics or water tablets, angiotensin-converting enzyme (ACE) inhibitors, angiotensin-II antagonists or beta-blockers.
- Probenecid (used to treat gout).
- Calcineurin inhibitors or immunosuppresive medicines (used to prevent organ rejection after a transplant), such as ciclosporin or tacrolimus.
- Intrauterine device (used as contraceptive to prevent pregnancy).
- Lithium (used to treat mood disorders).
- Methotrexate (used to treat cancer and rheumatoid arthritis/inflammation in your joints).
- Cholestyramine (used to lower cholesterol levels).
- Medicines which may affect certain enzymes known as CYP2C9 and/or CYP3A4 such as sulphonylureas and nateglinide (used to reduce your blood sugar levels).
- Pemetrexed (used in the treatment of cancer).

MELZY with alcohol

Do not drink alcohol during treatment with MELZY as it may increase your risk of bleeding.

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 health care provider for advice before taking MELZY.

Do not take MELZY if you are pregnant or breastfeeding your baby.

Driving and using machines

MELZY may cause blurred vision, dizziness, drowsiness and vertigo (a spinning sensation) and affect your ability to drive a vehicle or use machinery.

It is not always possible to predict to what extent MELZY may interfere with your daily activities.

Do not engage in the above activities until you are aware of the measure to which MELZY affects you.

MELZY contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MELZY.

3. How to take MELZY

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

Always take MELZY exactly as your doctor has told you. Check with your doctor if you are not sure.

The maximum daily dose of MELZY is 15 mg.

The dose depends on the medical condition which is being treated. Your doctor will let you know how much you should take.

For the treatment of painful osteoarthritis:

The usual dose is 7,5 mg a day. Your doctor may increase your dose to 15 mg a day, if necessary.

For the treatment of rheumatoid arthritis and ankylosing spondylitis:

The usual dose is 15 mg a day. Your doctor may reduce your dose to 7,5 mg a day depending on your response to the treatment.

For the treatment of acute sciatica:

The usual dose is 7,5 mg a day. If there is no improvement in your condition, your doctor may increase your dose to 15 mg a day.

If you are an elderly patient, have severe kidney disease and are on haemodialysis (treatment to filter wastes and water from your blood), have a history of gastrointestinal disease (a condition affecting your stomach or intestines) or risk factors for heart disease, your doctor may restrict your dose to 7,5 mg a day.

Swallow the tablets as a single dose with water or another drink, with food.

Your doctor will tell you how long your treatment with MELZY will last. You should use the lowest effective dose for the shortest period necessary to control symptoms, as this may help to reduce side effects.

If you have the impression that the effect of MELZY is too strong or too weak, or after several days you do not feel any improvement in your condition, tell your doctor or pharmacist.

If you take more MELZY than you should

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

Symptoms of overdose may include:

- Lack of energy and enthusiasm, drowsiness, nausea, vomiting, stomach pain or bleeding. In severe cases overdose may result in high blood pressure, kidney failure, liver damage, slow and infective breathing, coma, convulsions/fits and heart failure. Allergic reactions may also occur following overdose.

If you forget to take MELZY

Take the missed dose as soon as you remember. However, if it is almost time for your next

dose, continue to take the next tablet at the usual time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

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

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

- Swelling of your hands, feet, ankles, face, lips, eyelids, mouth or throat, which may cause difficulty in swallowing or breathing or wheezing.
- Bronchospasm or asthma (tightening of your chest causing difficulty/noisy breathing, shortness of breath or coughing), especially if you are allergic to aspirin or other NSAIDs.
- Rash or itching.
- Fainting.
- Stroke (sudden numbness/weakness in your face, arm or leg, especially on one side of your body).
- Heart attack (chest pain, weakness, shortness of breath).

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

- Swelling of your feet, legs, ankles or arms due to accumulation of fluid.
- Changes in the way your heart beats, such as pounding of your heart, beating faster than normal or irregular heartbeat.
- Heart failure (a condition where your heart is unable to pump blood around the body

properly with symptoms such as shortness of breath, fatigue and swelling in your legs, ankles and feet).

- Severe forms of skin reactions, sometimes accompanied by fever, causing a painful, blistering or peeling skin rash. These may be signs of a condition known as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).
- Drug reaction or rash with eosinophilia and systemic symptoms (DRESS syndrome) with symptoms such as skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cell).
- Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, painful, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin condition called “erythema multiforme”.
- Yellowing of the skin and eyes, dark urine, fever and tiredness, which may be symptoms of liver problems such as hepatitis (inflammation of the liver), abnormal liver function tests.
- Passing less urine than is normal for you (urinary retention), or additional swelling due to fluid retention, nausea, fatigue (kidney damage/failure).
- Nephrotic syndrome (swelling around your eyes and in your feet and ankles, foamy urine and weight gain).
- Inflammatory kidney diseases (passing more or less urine than is normal for you, blood in your urine, dark urine, fever, nausea, vomiting), abnormal kidney functions tests, increased sodium or potassium levels.
- Stomach or intestinal ulcers/sores, with bleeding and/or perforation, which may be more severe if you are an elderly patient.
- Causing or worsening of colitis (inflammation of your colon with symptoms such as diarrhoea, usually with bloody or black-coloured stools and mucous, stomach pain and fever).
- Inflammation of your stomach (gastritis) (burning ache or pain, nausea, vomiting).
- Inflammation of your oesophagus (oesophagitis) (difficulty/painful swallowing, heartburn).
- Inflammation of your pancreas (pancreatitis) (severe pain in your abdomen and back,

nausea, vomiting, fever).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Anaemia (decreased number of red blood cells which can make your skin pale and cause weakness or breathlessness).
- Headache, dizziness, light-headedness.
- Heartburn, nausea (feeling sick), vomiting (being sick), diarrhoea, excessive gas (wind), constipation, stomach pain.
- Skin rash and/or itching.

Less frequent side effects:

- Abnormal blood test results due to disorders affecting the blood and blood-forming organs (e.g. decreased number of red blood cells, white blood cells or blood platelets which can make your skin pale, cause weakness or breathlessness, increase the risk of bleeding/bruising or make infections more likely).
- Changes in your mood (mostly feeling happy, occasionally irritated/unhappy), feeling confused, sleeplessness (insomnia), nightmares.
- Drowsiness.
- Visual disturbances (including blurred vision), conjunctivitis/“pink eye” (inflammation or infection of the membrane of your eye causing redness, itching and discharge).
- Vertigo (dizziness or spinning sensation), ringing sound in your ears.
- Increased blood pressure (dizziness, headache).
- Flushing (reddening of your face, neck or upper chest).
- Inflammation of the lining of your mouth with painful ulcers/sores and swelling (stomatitis).
- Excessive burping.
- Raised, itchy rash (urticaria).

- Increased sensitivity of your skin to sunlight.

Frequency unknown side effects:

- Disorientation.
- Female infertility (struggling to get pregnant).

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. 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 MELZY.

5. How to store MELZY

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MELZY contains

- The active substance is meloxicam.

  MELZY 7,5: Each tablet contains 7,5 mg meloxicam.

  MELZY 15: Each tablet contains 15 mg meloxicam.

- The other ingredients are colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K-30 and sodium citrate.

What MELZY looks like and contents of the pack

MELZY 7,5: Yellow, round, uncoated tablets with a flat face and bevelled edges, debossed with the logo “Z” on one side and breakline on the other side. Diameter: approximately 6,35 mm.
MELZY 15: Yellow, round, uncoated tablets with a flat face and bevelled edges, debossed with the logo “Z” on one side and breakline on the other side. Diameter: approximately 7,93 mm.

MELZY 7,5: 10 tablets are packed into aluminium/PVdC blister strips. Each outer carton contains 3 blister strips.
MELZY 15: 10 tablets are packed into aluminium/PVdC blister strips. Each outer carton contains 1 or 3 blister strips.

Not all pack sizes may be marketed.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd
Southdowns Office Park
Building B, G/Floor
22 Karee Street
Centurion 0157
Tel: 012 748 6400

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