Front Side

435 mm

360 mm

SCHEDULING STATUS: S3

1. NAME OF THE MEDICINE

MACLUTEK 10 mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10,4 mg of montelukast sodium which is the molar equivalent to 10,0 mg of free acid.
MACLUTEK 10 mg contains sugar (lactose monohydrate 115,90 mg)
Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablets.
Beige colour, rounded square shaped, biconvex, film coated tablet debossed with 'CL 26' on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
MACLUTEK 10 mg is indicated in adults and children 15 years of age and older for the prophylaxis and chronic treatment of atopic asthma.
In those adult asthmatic patients, in whom **MACLUTEK 10 mg** is indicated in asthma, it may also provide some symptomatic relief of seasonal allergic rhinitis.

4.2 Posology and method of administration
Posology:
MACLUTEK 10 mg should be taken once daily in the evening.
Adults and Children 15 years of age and older with Atopic Asthma with or without Seasonal Allergic Rhinitis:
The dosage for adults 15 years of age and older, is one 10 mg film-coated tablet daily. Clinical studies in adults 15 years of age and older demonstrated there is no additional clinical benefit to montelukast doses above 10 mg once daily.

General Recommendations:
A therapeutic effect of **MACLUTEK 10 mg** on parameters of asthma control occurs within one day. **MACLUTEK 10 mg** can be taken with or without food. Patients should be advised to continue taking **MACLUTEK 10 mg**, while their asthma is controlled, as well as during periods of worsening asthma.
No dosage adjustment is necessary for the elderly, for patients with renal insufficiency, or mild to moderate hepatic impairment or for patients of either gender.

*Therapy with **MACLUTEK 10 mg** in Relation to Other Treatments for Asthma:*
MACLUTEK 10 mg can be added to a patient's existing treatment regimen. A gradual reduction of the dose of inhaled corticosteroids may be possible under medical supervision.

Method of administration:
Oral use.

4.3 Contraindications
MACLUTEK 10 mg is contraindicated in:
- Hypersensitivity to montelukast or any component of **MACLUTEK 10 mg.**

4.4 Special warnings and precautions for use
General:
The efficacy of oral **MACLUTEK 10 mg** for the treatment of acute asthma attacks has not been established. **MACLUTEK 10 mg** should not be used as monotherapy for the treatment and management of exercise-induced bronchospasm. Patients who have exacerbations of asthma after exercise should continue to use their usual regimen of inhaled beta-agonists as prophylaxis and have available for rescue a short-acting inhaled beta-agonist.

MACLUTEK 10 mg is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Patients should be advised to have appropriate rescue medication available. Therapy with **MACLUTEK 10 mg** can be continued during acute exacerbations of asthma.

While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, **MACLUTEK 10 mg** should not be abruptly substituted for inhaled or oral corticosteroids.
There are no data demonstrating that oral corticosteroid can be reduced when **MACLUTEK 10 mg** is given concomitantly.
In rare cases, patients on therapy with anti-asthma agents including montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These cases have been sometimes associated with the reduction or withdrawal of oral corticosteroid therapy. Although a causal relationship with leukotriene receptor antagonism has not been established, physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated.

Patients with known aspirin sensitivity should continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking **MACLUTEK 10 mg.** Although **MACLUTEK 10 mg** is effective in improving airway function in asthmatics with documented aspirin sensitivity, it has not been shown to truncate bronchoconstrictor response to aspirin and other non-steroidal anti-inflammatory medicines in aspirin-sensitive asthmatic patients.

Renal insufficiency:
Since montelukast and its metabolites are not excreted in the urine, the pharmacokinetics of montelukast were not evaluated in patients with renal insufficiency. No dosage adjustment is recommended in these patients.

Use in Elderly:
In clinical studies, there were no age-related differences in the efficacy or safety profiles of **MACLUTEK 10 mg.**

Eosinophilic Conditions:
Patients on therapy with **MACLUTEK 10 mg** may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal association between **MACLUTEK 10 mg** and these underlying conditions has not been established (see section 4.8).

Lactose intolerance
MACLUTEK 10 mg contains lactose.
Patients with rare hereditary conditions of galactose intolerance e.g. galactosaemia the Lapp lactase deficiency, glucose-galactose malabsorption should not take **MACLUTEK 10 mg.**

Neuropsychiatric events
Neuropsychiatric events have been reported in adults, adolescents and children taking **MACLUTEK 10 mg** (see section 4.8). Patients and medical practitioners should be alert for neuropsychiatric events. Patients and/or caregivers should be instructed to notify their medical practitioner if these changes occur. Prescribers should carefully evaluate continuing treatment with **MACLUTEK 10 mg** if such events occur.

MACLUTEK 10 mg
PM03844401

Information for Patients
- Patients should be advised to take **MACLUTEK 10 mg** daily as prescribed, even when they are asymptomatic, as well as during periods of worsening asthma, and to contact their physicians if their asthma is not well controlled.
- Patients should be advised that oral tablets of **MACLUTEK 10 mg** are not for the treatment of acute asthma attacks. They should have appropriate short-acting inhaled beta-agonist medication available to treat asthma exacerbations.
- Patients should be advised that, while using **MACLUTEK 10 mg**, medical attention should be sought if short-acting inhaled bronchodilators are needed more often than usual, or if more than the maximum number of inhalations of short-acting bronchodilator treatment prescribed for a 24-hour period are needed.
- Patients receiving **MACLUTEK 10 mg** should be instructed not to decrease the dose or stop taking any other anti-asthma medications unless instructed by a physician.
- Patients who have exacerbations of asthma after exercise should be instructed to continue to use their usual regimen of inhaled beta-agonists as prophylaxis unless otherwise instructed by their physician. All patients should have available for rescue a short-acting inhaled beta-agonist.
- Patients with known aspirin sensitivity should be advised to continue avoidance of aspirin or non-steroidal anti-inflammatory agents while taking **MACLUTEK 10 mg.**

4.5 Interaction with other medicines and other forms of interaction
MACLUTEK 10 mg may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma, and seasonal allergic rhinitis. In medicine -interactions studies, the recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medicines: theophylline, prednisone, prednisolone, oral contraceptives (ethinyl oestradiol/norethindrone 35/1), terfenadine, digoxin and warfarin.

The area under the plasma concentration – time curve (AUC) for montelukast was decreased approximately 40 % in subjects with co-administration of phenobarbital. No dosage adjustment for **MACLUTEK 10 mg** is recommended.

Since montelukast is metabolised by CYP 3A4, 2C8 and 2C9 caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin.

In vitro studies have shown that montelukast is a potent inhibitor of CYP2C8. However, data from a clinical drug-drug interaction study involving montelukast and rosiglitazone (a probe substrate representative of medicines primarily metabolised by CYP2C8) demonstrated that montelukast did not significantly inhibit CYP2C8 *in vivo*. Therefore, montelukast is not anticipated to alter the metabolism of drugs metabolized by this enzyme (e.g. paclitaxel, rosiglitazone, and repaglinide).

In vitro studies have shown that montelukast is a substrate of CYP 2C8 and to a less significant extent of 2C9 and 3A4. In a clinical medicine interaction study involving montelukast and gemfibrozil (an inhibitor of both CYP 2C8 and 2C9) gemfibrozil increased the systemic exposure of montelukast. No routine dosage adjustment of montelukast is required upon co-administration with gemfibrozil or other potent inhibitors of CYP 2C8, but the medical practitioner should be aware of the potential for an increase in adverse reactions.

Based on *in-vitro* data, clinically important medicine interactions with less potent inhibitors of CYP 2C8 (e.g. trimethoprim) are not anticipated. Co-administration of montelukast with itraconazole, a strong inhibitor of CYP 3A4, resulted in no significant increase in the systemic exposure of montelukast.

4.6 Fertility, pregnancy and lactation
The safety of this medicine in pregnant and lactating women has not been established.

Since there are no controlled studies in pregnant or breastfeeding women, montelukast should not be used during pregnancy or by breastfeeding mothers. It is not known if **MACLUTEK 10 mg** is excreted in human milk.

During worldwide marketing experience, congenital limb defects have been reported in the off-spring of women being treated with MACLUTEK 10 mg during pregnancy. A causal relationship between these events and MACLUTEK 10 mg has not been established.

4.7 Effects on ability to drive and use machines
MACLUTEK 10 mg have no or negligible influence on the ability to drive and use machines. However, individuals have reported drowsiness or dizziness.

4.8 Undesirable effects:
Side-effects generally did not require discontinuation of therapy. The following adverse reactions have been reported in association with **MACLUTEK 10 mg.** Adverse reactions are listed by System Organ Class in the table below. Frequency categories were estimated based on relevant clinical trials. The safety profile did not change with prolonged treatment during long-term studies.

System Organ Class	Frequency	Undesirable effects
Infections and infestations	Frequent	Upper respiratory infection.
Blood and lymphatic system disorders	Less frequent	Increased bleeding tendency, thrombocytopenia
Immune system disorders	Less frequent	Hypersensitivity reactions including anaphylaxis, hepatic eosinophilic infiltration.
Psychiatric disorders	Less frequent	Dream abnormalities including nightmares, insomnia, somnambulism, anxiety, agitation including aggressive behaviour or hostility, depression, psychomotor hyperactivity (including irritability, restlessness, tremor). Disturbance in attention, memory impairment, tic, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), obsessive-compulsive symptoms, dysphemia
Nervous system disorders:	Frequent:	Headache.
	Less frequent	Dizziness, drowsiness, paraesthesia / hypoesthesia, seizures.
Cardiac disorders:	Less frequent	Palpitations
Respiratory, thoracic and mediastinal disorders	Less frequent	Epistaxis, Churg-Strauss Syndrome (see section 4.4). Pulmonary eosinophilia
Gastrointestinal disorders	Frequent	Abdominal pain Diarrhea, nausea, vomiting
	Less frequent	Dry mouth, dyspepsia.
Hepatobiliary disorders	Frequent	Elevated levels of serum transaminases - Alanine Amino-Transferase (ALT) and Aspartate Amino Transferase (AST).
	Less frequent:	Hepatitis (including cholestatic, hepatocellular and mixed pattern liver injury).
Skin and subcutaneous tissue disorders:	Frequent	Rash.
	Less frequent	Bruising, urticaria, pruritus, Angioedema. Erythema nodosum, erythema multiforme.
Musculoskeletal and connective tissue	Less frequent	Arthralgia, myalgia including muscle cramps.
Renal and urinary disorders	Less frequent	Enuresis in children
General disorders and administration site conditions:	Frequent	Pyrexia
	Less frequent	Asthenia/fatigue, malaise, oedema.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/8.

4.9 Overdose
No specific information is available on the treatment of overdosage with **MACLUTEK 10 mg.**
There have been reports of acute overdosage in postmarketing experience and clinical studies with **MACLUTEK 10 mg.** These include reports in adults and children with a dose as high as 1 000 mg. The clinical and laboratory findings observed were consistent with the safety profile in adults and paediatric patients.
There were no adverse experiences reported in the majority of overdosage reports. The most frequently occurring adverse experiences were consistent with the safety profile of **MACLUTEK 10 mg** and included abdominal pain, somnolence, thirst, headache, vomiting and psychomotor hyperactivity.

It is not known whether montelukast is dialyzable by peritoneal or haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

Category and class: A.10.2.2 Other anti-asthmatics
Pharmacotherapeutic group: Leukotriene receptor antagonists
ATC code: R03DC03.

5.1 Pharmacodynamic properties
Mechanism of Action
The cysteinyl leukotrienes (LTC_4, LTD_4, LTE_4), are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 ($CysLT_1$) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis. In asthma, leukotriene-mediated effects include a number of airway actions, including bronchoconstriction, mucous secretion, vascular permeability, and eosinophil recruitment.
In allergic rhinitis, CysLTs are releases from the nasal mucosa after allergen exposure during both early-and late-phase reactions and are associated with symptoms of allergic rhinitis. Intranasal challenge with CysLTs has been shown to increase nasal airway resistance and symptoms of nasal obstruction.
Montelukast is an orally active compound whichbinds with high affinity and selectivity to the CysLT, receptor (in preference to other pharmacologically important airway receptors such as the prostanoid, cholinergic, or beta-adrenergic receptor). Montelukast inhibits physiological actions of LTC_4, LTD_4, and LTE, at the CysLT, receptor without agonist activity.

Pharmacodynamic effects
Montelukast causes potent inhibition of airway cysteinyl leukotriene receptors as demonstrated by the ability to inhibit bronchoconstriction due to inhaled LTD_4 in asthmatic patients.

5.2 Pharmacokinetic properties
Absorption:
Montelukast is absorbed following oral administration.
For the 10 mg film-coated tablet, the mean peak plasma concentration (C_{max}) is achieved 3 hours (T_{max}) after administration in adults in the fasted state. The mean oral bioavailability is 64 %. The oral bioavailability and C_{max} are not influenced by a standard meal.

Distribution
Montelukast is more than 99 % bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8 to 11 litres. Studies in rats with radiolabeled montelukast indicate minimal distribution across the blood-brain barrier. In addition, concentrations of radiolabeled material at 24 hours postdose were minimal in all other tissues.

Biotransformation
Montelukast is extensively metabolized in the liver. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and paediatric patients.
In vitro studies using human liver microsomes indicate that cytochrome P450 3A4 and 2C9 are involved in the metabolism of montelukast. Based on further in vitro results in human liver microsomes, therapeutic plasma concentrations of montelukast do not inhibit cytochromes P450 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6.

Elimination:
The plasma clearance of montelukast averages 45 ml/min in healthy adults. Following an oral dose of radiolabeled montelukast, 86 % of the radioactivity was recovered in 5-day faecal collections and less than 0,2 % was recovered in urine. Coupled with estimates of montelukast oral bioavailability, this indicates montelukast and its metabolites are excreted almost exclusively via the bile.
In several studies, the mean plasma half-life of montelukast ranged from 2,7 to 5,5 hours in healthy young adults. The pharmacokinetics of montelukast are nearly linear for oral doses up to 50 mg. No difference in pharmacokinetics was noted between dosing in the morning or in the evening. During once-daily dosing with 10 mg montelukast, there is little accumulation of the parent drug in plasma (approximately 14 %).

Hepatic Insufficiency
Patients with mild-to-moderate hepatic insufficiency and clinical evidence of cirrhosis had evidence of decreased metabolism of montelukast resulting in approximately 41 % higher mean montelukast area under the plasma concentration curve (AUC) following a single 10 mg dose. The elimination of montelukast is slightly prolonged compared with that in healthy subjects (mean half-life, 7,4 hours).

No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency. There are no clinical data in patients with severe hepatic insufficiency (Child-Pugh score greater than 9).

Elderly
The pharmacokinetic profile and the oral bioavailability of a single 10 mg oral dose of montelukast are similar in elderly and younger adults. The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required.

Renal insufficiency
Because montelukast and its metabolites are eliminated by the biliary route, no dose adjustment is anticipated to be necessary in patients with renal impairment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Contains Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropylcellulose, disodium edetate, magnesium stearate. The tablets are coated with coating made up of hypromellose, titanium dioxide (C.I. No.77891), ferric oxide yellow (C.I.No.77492), ferric oxide red (C.I. No.77491).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Blister pack: 24 months from the manufacturing date.
HDPE Container pack: 36 months from the manufacturing date.

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from light and moisture.
Keep the blister in the carton until required for use.
Keep the HDPE container tightly closed.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container
1) Blister Pack:
Tablets are packed in cold form laminate 25 µm OPA/45 µm aluminum foil/60 µm PVC as the forming material and 30 µ aluminium plain foil/ 6-8 gsm heat seal lacquer as the lidding material, packed in a pre-printed carton.
Pack size include 10, 28 or 30 tablets.

2) HDPE Container:
Tablets are packed in round, white 40 ml HDPE container with 33-400 mm neck finish which are closed with 33 mm child resistant closure with pulp and heat seal liner and packed in outer carton. Each HDPE container contains 2 sachets of 1 g silica gel.
Pack size include 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirement.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton 2061, South Africa.

8. REGISTRATION NUMBER(S)

47/10.2.2/0596

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 MARCH 2022

10. DATE OF REVISION OF THE TEXT

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

MACLUTEK 10 mg (Film-coated Tablets)
Montelukast 10 mg
Contains sugar (Lactose monohydrate 115,90 mg)

Read all of this leaflet carefully before you start taking MACLUTEK 10 mg
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MACLUTEK 10 mg** 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 **MACLUTEK 10 mg** is and what it is used for
2. What you need to know before you take **MACLUTEK 10 mg**
3. How to take **MACLUTEK 10 mg**
4. Possible side effects
5. How to store **MACLUTEK 10 mg**
6. Contents of the pack and other information

1. What MACLUTEK 10 mg is and what it is used for

MACLUTEK 10 mg contains the active ingredient montelukast that is used for the treatment of asthma.
Your doctor has prescribed **MACLUTEK 10 mg** to treat your asthma, including preventing your asthma symptoms.
You should take **MACLUTEK 10 mg** as your doctor or healthcare provider told you as this may help reduce the severity of your asthma and the frequency of your asthma attacks.
MACLUTEK 10 mg blocks substances in your lungs called leukotrienes that cause narrowing and swelling (inflammation) of airways.
If you are using **MACLUTEK 10 mg** for your asthma, **MACLUTEK 10 mg** may also provide some symptomatic relief of seasonal allergic rhinitis.

What are seasonal allergies?
- Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds.
- The daytime and nighttime symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. What you need to know before you take MACLUTEK 10 mg

Do not take MACLUTEK 10 mg
- If you are allergic to montelukast or any of the other ingredients of **MACLUTEK 10 mg.**

Warnings and precautions
Take special care with **MACLUTEK 10 mg:**
If your asthma symptoms get worse, or if you need to increase the use of your emergency asthma pump for asthma attacks, you should contact your doctor immediately.

Oral **MACLUTEK 10 mg** tablets is not for the treatment of acute asthma attacks. If an attack occurs, you should follow the instructions your doctor has given you for that situation.
Always have your emergency asthma pump or emergency medicine for asthma attacks with you.

It is important that you take all asthma medications prescribed for you by your doctor. **MACLUTEK 10 mg** should not be used instead of other asthma medications your doctor has prescribed for you.

If your doctor has prescribed a medicine for you to use before exercise, you should keep using that medicine.

If your asthma is known to be made worse by aspirin, do not take aspirin and other non-steroidal anti-inflammatory medicines. Ask your doctor, pharmacist or other healthcare professional if you are not sure.

Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness (pyrexia), Typically tingling or pricking / pins and needles (paraesthesia), numbness (hypoesthesia), worsening of lung symptoms, and/or rash, you should consult your doctor.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with **MACLUTEK 10 mg** (see section 4). If you develop such symptoms while taking **MACLUTEK 10 mg**, you should consult your doctor.

Back Side

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Other medicines and MACLUTEK 10 mg
Always tell your doctor, pharmacist or other healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
The use of **MACLUTEK 10 mg** with other medicines may be cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice, if you are unsure.

It is particularly important that you should tell your doctor if you are taking the following medicines before starting **MACLUTEK 10 mg:**
- Phenobarbital (used for treatment of epilepsy)
- Phenytoin (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections).
- Gemfibrozil (used for high fat levels in your blood (cholesterol)).

MACLUTEK 10 mg with food, drink and alcohol:
MACLUTEK 10 mg can be taken with or without food.

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 professional for advice before taking this medicine.
The safety of **MACLUTEK 10 mg** in pregnant and breastfeeding women has not been established.
MACLUTEK 10 mg has not been studied in pregnant or breastfeeding women.
It is not known if **MACLUTEK 10 mg** is excreted in human milk.

Driving and using Machines
You may experience dizziness and or drowsiness when taking **MACLUTEK 10 mg.** You should not drive or operate machinery until you know how **MACLUTEK 10 mg** affects you.

MACLUTEK 10 mg contains lactose
Lactose: Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **MACLUTEK 10 mg.**

3. How to take MACLUTEK 10 mg

- Do not share medicines prescribed for you with any other person.
- Always take **MACLUTEK 10 mg** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose of **MACLUTEK 10 mg** for adults and adolescents 15 years and older, for the treatment of asthma with or without seasonal allergic rhinitis is one 10 mg tablet once a day in the evening.
- Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)
- Your doctor will tell you how long your treatment with **MACLUTEK 10 mg** will last. Do not stop treatment early. If you have the impression that the effect of **MACLUTEK 10 mg** is too strong or too weak, tell your doctor or pharmacist.
- It is important to continue taking **MACLUTEK 10 mg** for as long as your doctor prescribes it in order to maintain control of your asthma. **MACLUTEK 10 mg** can treat your asthma only if you continue to take it.

If you take more MACLUTEK 10 mg than you should
In the event of overdosage consult your doctor, pharmacist or other healthcare provider. If neither is available contact the nearest hospital or poison control center and take your **MACLUTEK 10 mg** with you.
The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting and hyperactivity.

If you forget to take MACLUTEK 10 mg
You should take **MACLUTEK 10 mg** as your doctor has prescribed. However, if you miss a dose, resume the usual schedule of one tablet once daily.
Do not take a double dose to make up for a forgotten dose.

If you stop taking MACLUTEK 10 mg
MACLUTEK 10 mg can treat your asthma only if you continue to take it.
It is important to continue taking **MACLUTEK 10 mg** for as long as your doctor prescribes. It will help control your asthma.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

MACLUTEK 10 mg can have side-effects.
Not all the side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MACLUTEK 10 mg**, please consult your doctor, pharmacist or health care professional for advice.
If any of the following happens, stop taking **MACLUTEK 10 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:
Symptoms of a severe allergic reaction such as -
- Swelling (oedema) of face, tongue or throat.
- Difficulties in swallowing.
- Hives and difficulties in breathing.
- Severe skin reactions that can include blistering of the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MACLUTEK 10 mg.** You may need urgent medical attention or hospitalization.
Tell your doctor if you develop a combination of symptoms such as:
- A flu-like illness (Pyrexia).
- Typically tingling or pricking / pins and needles (Paraesthesia).
- Numbness of the arms and legs (Hypoesthesia).
- Worsening of lung symptoms (pulmonary eosinophilia).
- Rash.
- Inflammation of blood vessels (Churg-Strauss syndrome).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following side-effects:
Frequent side effects:
- Upper respiratory infection
- Headache
- Abdominal pain, diarrhoea, nausea, vomiting
- Liver damaged or inflamed [Elevated levels of serum transaminases - Alanine Amino-Transferase (ALT) and Aspartate Amino Transferase (AST)]
- Rash
- A flu-like illness / raised body temperature (Pyrexia)

Less frequent side effects
- Increased bleeding tendency, Low platelet level (thrombocytopenia)
- Dream abnormalities including nightmares, problems falling and staying asleep (insomnia), sleepwalking (somnambulism), feelings of worry (anxiety), agitation including aggressive behaviour or hostility, depression, psychomotor hyperactivity (including irritability, restlessness, tremor), disturbance in attention, memory impairment, tic, hallucinations, disorientation, suicidal thinking and behaviour (suicidality), obsessive-compulsive symptoms, dysphemia
- Dizziness, drowsiness, typically tingling or pricking / pins and needles (paraesthesia), numbness (hypoesthesia), seizure
- Rapid, strong or irregular heartbeat (Palpitations)
- Nosebleeds (Epistaxis), inflammation of blood vessels (Churg-Strauss Syndrome), pulmonary eosinophilia
- Dry mouth, indigestion
- Hepatitis (including cholestatic, hepatocellular and mixed pattern liver injury)
- Bruising, hives (urticaria), pruritus, Painless swelling under the skin (angioedema), tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme)
- Pain in a joint (Arthralgia), myalgia including muscle cramps
- Bedwetting (Enuresis) in children
- Weakness or decreased muscle strength (Asthenia), tiredness (fatigue), feeling unwell (malaise), swelling (oedema)

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

Reporting of side effects
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

5. How to store MACLUTEK 10 mg

Store at or below 25 °C.
Protect from light and moisture.
Keep the blister in the carton until required for use.
Keep the HDPE container tightly closed.
KEEP OUT OF REACH OF CHILDREN
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What MACLUTEK 10 mg contains
- The active substance is Montelukast sodium 10,4 mg equivalent to 10 mg of montelukast.
- The other ingredients are Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropylcellulose, disodium edetate, magnesium stearate. The tablets are coated with coating made up of hypromellose, titanium dioxide (C.I. No.77891), ferric oxide yellow (C.I. No.77492), ferric oxide red (C.I. No.77491).

What MACLUTEK 10 mg looks like and contents of the pack
Beige colour, rounded square shaped, biconvex, film coated tablet debossed with 'CL 26' on one side and plain on the other side.

Blister Pack:
Tablets are packed in cold form laminate 25 µm OPA/45 µm aluminium foil/60 µm PVC as the forming material and 30 µ aluminium plain foil/ 6-8 gsm heat seal lacquer as the lidding material, packed in a pre-printed carton.
Pack size include 10, 28 or 30 tablets.

HDPE Container:
Tablets are packed in round, white 40 ml HDPE container with 33 - 400 mm neck finish which are closed with 33 mm child resistant closure with pulp and heat seal liner and packed in outer carton.
Each HDPE container contains 2 sachets of 1 g silica gel.
Pack size include 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12.
Alberton 2061, South Africa.

This leaflet was last revised in
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Registration number
47/10.2.2/0596

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com/or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

MACLUTEK 10 mg (Filmbedekte Tablette)
Montelukast 10 mg
Bevat suiker (115,90 mg Laktosemonohidraat)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy MACLUTEK 10 mg begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter of jou apteker, indien jy verdere vrae het.
- **MACLUTEK 10 mg** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **MACLUTEK 10 mg** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **MACLUTEK 10 mg** gebruik
3. Hoe om **MACLUTEK 10 mg** te gebruik
4. Moontlike newe-effekte
5. Hoe om **MACLUTEK 10 mg** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat MACLUTEK 10 mg is en waarvoor dit gebruik word

MACLUTEK 10 mg bevat die aktiewe bestanddeel montelukast wat gebruik word vir die behandeling van asma.
Jou dokter het **MACLUTEK 10 mg** voorgeskryf om jou asma te behandel, insluitend vir die voorkoming van jou asma simptome.
Jy moet **MACLUTEK 10 mg** neem soos jou dokter of gesondheidsorgverskaffer vir jou gesê het, aangesien dit kan help om die ems van jou asma en die frekwensie van jou asma-aanvalle te verminder.
MACLUTEK 10 mg blokkeer stowwe in jou longe, genoem leukotriene, wat vernouing en swelling (ontsteking) van lugweë veroorsaak.
Indien jy **MACLUTEK 10 mg** gebruik vir jou asma, kan **MACLUTEK 10 mg** ook 'n mate van simptomatiese verligting van seisonale allergiese rinitis bied.
Wat is seisonale allergieë?
- Seisonale allergieë (ook bekend as hooikoors of seisonale allergiese rinitis) is 'n allergiese reaksie wat dikwels veroorsaak word deur luggedraagde stuifmeel van bome, grasse en onkruid.
- Die dag- en nagsimptome van seisoenale allergieë kan tipies die volgende insluit: verstopte, loperige, jeukende neus; nies; waterige, geswelde, rooi, jeukende oë.

2. Wat jy behoort te weet voordat jy MACLUTEK 10 mg gebruik

Moet nie MACLUTEK 10 mg neem nie
- Indien jy allergies vir montelukast, of enige van die ander bestanddele van **MACLUTEK 10 mg** is.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **MACLUTEK 10 mg**
Jy moet onmiddellik jou dokter kontak, indien jou asma simptome erger word, of indien jy jou nood asmapompie meer dikwels vir asma-aanvalle moet gebruik.

Orale **MACLUTEK 10 mg** tablette is nie vir die behandeling van akute asma-aanvalle nie. Indien 'n aanval voorkom, moet jy die instruksies volg wat jou dokter vir jou gegee het vir daardie situasie.
Hou altyd jou nood-asmapompie of noodmedisyne vir asma-aanvalle by jou

Dit is belangrik dat jy al die asma medikasie wat deur jou dokter vir jou voorgeskryf is, neem. **MACLUTEK 10 mg** moet nie gebruik word in die plek van ander asma medisyne wat jou dokter vir jou voorgeskryf het nie.

Indien jou dokter 'n medisyne vir jou voorgeskryf het om te gebruik voor oefening, moet jy daardie medisyne aanhou gebruik.

Indien jy weet dat jou asma deur aspirien vererger word, moet nie aspirien en ander nie-steroïed anti-inflammatoriese middels gebruik nie. Vra jou dokter, apteker of ander professionele gesondheidsorgwerker indien jy nie seker is nie.

Enige pasiënt wat anti-asma medisyne gebruik, moet bewus wees dat indien jy 'n kombinasie van simptome ontwikkel soos 'n griepagtige siekte (pireksie), tipiese tinteling of prikkeling/spelde en naalde (parestesie), gevoelloosheid (hipoëstesie), verergering van longsimptome, en/of uitslag, moet jy jou dokter inlig.

Pasiënte moet bewus wees daarvan dat verskeie neuropsigiatriese gebeure (byvoorbeeld gedrag en gemoedsverwante veranderinge) in volwassenes, adolessente en kinders, met **MACLUTEK 10 mg** aangemeld is (sien afdeling 4). Indien jy sulke simptome ontwikkel terwyl jy **MACLUTEK 10 mg** neem, moet jy jou dokter raadpleeg.

Ander medisyne en MACLUTEK 10 mg
Vertel altyd vir jou dokter, apteker of ander professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Die gebruik van **MACLUTEK 10 mg** saam met ander medisyne kan ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies indien jy onseker is.

Dit is veral belangrik dat jy jou dokter moet vertel indien jy die volgende medisyne neem voordat met **MACLUTEK 10 mg** begin word:
- Fenobarbitoon (gebruik vir die behandeling van epilepsie).
- Fenitoïen (gebruik vir die behandeling van epilepsie).
- Rifampisien (gebruik vir die behandeling van tuberkulose en sommige ander infeksies).
- Gemfibrosil (gebruik vir hoë vetvlakke in jou bloed (cholesterol)).

MACLUTEK 10 mg met voedsel, drank en alkohol
MACLUTEK 10 mg kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, dink dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy hierdie medisyne neem.
Die veiligheid van **MACLUTEK 10 mg** in swanger en borsvoedende vrouens is nie vasgestel nie.
MACLUTEK 10 mg is nie in swanger of borsvoedende vrouens bestudeer nie.
Dit is nie bekend of **MACLUTEK 10 mg** in menslike melk uitgeskei word nie.

Bestuur en gebruik van masjinerie
Jy kan duiseligheid en/of lomerigheid ervaar wanneer jy **MACLUTEK 10 mg** neem. Jy moet nie bestuur of masjinerie beheer totdat jy weet hoe **MACLUTEK 10 mg** jou affekteer nie.

MACLUTEK 10 mg bevat laktose
Laktose: Pasiënte met die seldsame oorerflike toestande van laktose of galaktose-intoleransie moet nie **MACLUTEK 10 mg** neem nie.

3. Hoe om MACLUTEK 10 mg te gebruik

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
- Gebruik altyd **MACLUTEK 10 mg** presies soos jou dokter of apteker jou beveel het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.
- Die gewone dosis **MACLUTEK 10 mg** vir volwassenes en adolessente 15 jaar en ouer, vir die behandeling van asma met of sonder seisoenale allergiese rinitis, is een 10 mg tablet een keer per dag, in die aand.
- Neem die tablette met 'n voldoende hoeveelheid vloeistof (bv. een glas water).
- Jou dokter sal vir jou sê hoe lank jou behandeling met **MACLUTEK 10 mg** sal aanhou. Moet nie met die behandeling vroeër ophou nie. Praat met jou dokter of apteker, indien jy onder die indruk is dat die effek van **MACLUTEK 10 mg** te sterk of te swak is.
- Dit is belangrik om aan te hou om **MACLUTEK 10 mg** te gebruik vir so lank as wat jou dokter dit voorskryf om sodoende beheer oor jou asma te behou. **MACLUTEK 10 mg** kan jou asma behandel, slegs as jy aanhou om dit te gebruik.

Indien jy meer MACLUTEK 10 mg neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of giftebeheersentrum en neem jou **MACLUTEK 10 mg** saam met jou.
Die simptome wat die mees algemeenste met oordosering in volwassenes en kinders aangemeld is, sluit abdominale pyn, slaperigheid, dors, hoofpyn, braking en hiperaktiwiteit in.

Indien jy vergeet om MACLUTEK 10 mg te neem
Jy moet **MACLUTEK 10 mg** neem soos jou dokter dit voorgeskryf het. Indien jy egter 'n dosis oorslaan, hervat die gewone skedule van een tablet een keer per dag.
Moet nie 'n dubbele dosis neem om vir die oorgeslane dosis op te maak nie.

Indien jy ophou om MACLUTEK 10 mg te neem
MACLUTEK 10 mg kan jou asma behandel, slegs as jy aanhou om dit te gebruik.
Dit is belangrik om voort te gaan om **MACLUTEK 10 mg** te neem vir so lank as wat jou dokter dit voorskryf. Dit sal help om jou asma te beheer.
Indien jy enige verdere vrae oor die gebruik van hierdie medisyne het, vra jou dokter of apteker.

4. Moontlike newe-effekte

MACLUTEK 10 mg kan newe-effekte hê.
Nie al die newe-effekte wat vir hierdie medisyne aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy **MACLUTEK 10 mg** gebruik, raadpleeg asseblief jou dokter, apteker of professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **MACLUTEK 10 mg** te neem en vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
Simptome van 'n ernstige allergiese reaksie soos -
- Swelling (edeem) van gesig, tong of keel.
- Probleme om te sluk.
- Galbulte en probleme met asemhaling.
- Ernstige velreaksies wat blase op die vel kan insluit.

Al hierdie newe-effekte is baie ernstig. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op **MACLUTEK 10 mg** gehad het. Jy mag dringende mediese aandag of hospitalisasie nodig hê.
Vertel jou dokter indien jy 'n kombinasie van simptome ontwikkel soos:
- 'n Griepagtige siekte (Pireksie).
- Tipiese tinteling of prikkeling/spelde en naalde (Parestesie).
- Gevoelloosheid van die arms en bene (Hipoëstesie).
- Verergering van longsimptome (pulmonêre eosinofilie).
- Uitslag.
- Ontsteking van bloedvate (Churg-Strauss sindroom).

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende newe-effekte opmerk:
Gereelde newe-effekte:
- Boonste lugweginfeksie.
- Hoofpyn
- Abdominale pyn, diaree, naarheid, braking
- Lewerskade of -ontsteking [Verhoogde vlakke van serumtransaminases - Alanien Amino Transferase (ALT) en Aspartaat Amino Transferase (AST)]
- Uitslag
- 'n Griepagtige siekte/verhoogde liggaamstemperatuur (Pireksie).

Minder gereelde newe-effekte:
- Verhoogde bloedingsneiging, lae bloedplaatjievlak (trombositopenie)
- Ongewone drome, insluitend nagmerries, probleme om aan die slaap te raak en om aan die slaap te bly (insomnie), slaapwandeling (somnambulisme), gevoelens van bekommernis (angs), agitasie insluitend aggressiewe gedrag of vyandigheid, depressie, psigomotoriese hiperaktiwiteit (insluitend prikkelbaarheid, rusteloosheid, bewing), aandagversteuring , geheue inkorting, senutreiking, hallusinasies, disoriëntasie, selfmoordgedagtes en gedrag (selfmoord), obsessiewe-kompulsiewe simptome, warspraak
- Duiseligheid, lomerigheid, tipiese tinteling of prikkeling/spelde en naalde (parestesie), gevoelloosheid (hipoëstesie), aanvalle
- Vinnige, sterk of onreëlmatige hartklop (Palpitasies)
- Neusbloedings (Epistaksie), ontsteking van bloedvate (Churg-Strauss sindroom), pulmonêre eosinofilie
- Droë mond, slegte spysvertering
- Hepatitis (insluitend cholestatiese, hepatoselullêre en gemengde patroon lewerbesering)
- Kneusing, galbulte (urtikarie), pruritus, pynlose swelling onder die vel (angioedeem), teer rooi knoppe onder die vel mees algemeen op jou skeenbeen (knobbelhuidroosheid) en erge velreaksies (veelvuldige eriteem)
- Pyn in 'n gewrig (Artralgie), mialgie insluitend spierkrampe
- Bednatmaak (Enuresis) in kinders
- Swakheid of verminderde spierkrag (Astenie), moegheid (vermoeidheid), voel onwel (ongesteldheid), swelling (edeem)

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, **lig asseblief** jou dokter of apteker in.

Aanmelding van newe-effekte
Dit is belangrik om vermoedelike nadelige reaksies aan te meld na goedkeuring van die medisyne. Dit laat voortgesette monitering van die voordeel/risiko-balans van die medisyne toe. Gesondheidsorgverskaffers word gevra om enige vermoedelike nadelige reaksies aan SAHPRA te rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https: //www.sahpra.org.za/Publications/Index/8.

5. Hoe om MACLUTEK 10 mg te bewaar

Bewaar by of benede 25 °C.
Beskerm teen lig en vog.
Hou die stulpstrook in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houer dig toe.
BEWAAR BUITE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat MACLUTEK 10 mg bevat
- Die aktiewe bestanddeel is 10,4 mg natriummontelukast gelykstaande aan 10 mg montelukast.
- Die ander bestanddele is laktosemonohidraat, mikrokristallyne sellulose, natriumkruiskarmellose, hidroksipropielsellulose, dinatriumedeteat, magnesiumstearaat. Die tablette is bedek met 'n deklaag wat bestaan uit hipromellose, titaandioksied (C.I. Nr.77891), geel ysteroksied (C.I. Nr.77492), rooi ysteroksied (C.I. Nr.77491).

Hoe MACLUTEK 10 mg lyk en inhoud van die pak
Roomkleurige, afgeronde vierkantige, bikonvekse, filmbedekte tablet met 'CL 26' gedruk op die een kant en glad aan die ander kant.

Stulpverpakking:
Tablette word verpak in koue vorm gelamineerde 25 µm OPA/45 µm aluminiumfoelie/60 µm PVC as die vormingsmateriaal en 30 µm gewone aluminium foelie/6-8 gsm hittesëllak as die dekmateriaal, verpak in 'n voorafgedrukte karton.
Verpakkingsgrootte sluit 10, 28 of 30 tablette in.

HDPE houer:
Tablette word verpak in ronde, wit 40 ml HDPE houer met 33 - 400 mm nekafwerking wat toegemaak is met 33 mm kinderbestande sluiting met pulp en hittesëëlvoering en verpak word in 'n buitenste karton. Elke HDPE houer bevat 2 sakkies van 1 g silikagel.
Verpakkingsgrootte sluit 28 of 30 tablette in.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton 2061, Suid Afrika

Hierdie inligtingstuk was hersien in
22 Maart 2022.

Registrasienommer
47/10.2.2/0596

Toegang tot die ooreenstemmende Professionele inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com/of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

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MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: MACLUTEK 10 mg (Montelukast 10 mg film coated tablets)	
2. Country: South Africa - Private Market	3. Packaging component: Patient Information
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 435 (L) x 360 (W) mm
9. Design / Style: Booklet type	10. Item code No.: PM03844401
11. Artwork has been made: Actual Size	12. Pharma code No.: 31491 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: E:\ANDA Regulatory\South Africa\MACLUTEK\MACLUTEK 10 mg PI & PIL-PM03844401.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
01-09-2022	Vanita Rajool	01/09/22	02.09.22	02/09/22	03/09/22

QA Tanuja 03/09/22

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03844401		

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