Front Side

435 mm

360 mm

MACLUTEK 4/5 mg
CHEWABLE TABLETS
PM03843901

SCHEDULING STATUS: S3

1. NAME OF THE MEDICINE

MACLUTEK 4 mg chewable tablet
MACLUTEK 5 mg chewable tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MACLUTEK 4 mg chewable tablet
Each chewable tablet contains 4,16 mg of montelukast sodium equal to the molar equivalent of 4,0 mg of free acid.
MACLUTEK 4 mg chewable tablet. Sugar free. Contains sweetener (aspartame 1,2 mg per tablet)
MACLUTEK 5 mg chewable tablet
Each chewable tablet contains 5,2 mg of montelukast sodium equal to the molar equivalent of 5,0 mg of free acid.
MACLUTEK 5 mg chewable tablet. Sugar free. Contains sweetener (aspartame 1,5 mg per tablet).

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable tablet.
MACLUTEK 4 mg chewable tablet
Pink colour, oval, biconvex, uncoated chewable mottled tablet debossed with 'CL 55' on one side and plain on the other side.
MACLUTEK 5 mg chewable tablet
Pink colour, mottled, circular, biconvex, uncoated chewable tablet debossed with 'CL 56' on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
MACLUTEK 4 mg chewable tablet is indicated in paediatric patients 2 to 5 years of age for the prophylaxis and chronic treatment of atopic asthma.
MACLUTEK 5 mg chewable tablet is indicated in paediatric patients over 6 years of age for the prophylaxis and chronic treatment of atopic asthma.

4.2 Posology and method of administration
Posology:
MACLUTEK should be taken once daily in the evening.
MACLUTEK 4 mg Chewable Tablets:
Paediatric Patients 2 to 5 Years of age with Atopic asthma:
The dosage for paediatric patients 2 to 5 years of age is one 4 mg chewable tablet daily to be taken at bedtime.
MACLUTEK 5 mg Chewable Tablets:
Paediatric Patients 6 to 14 Years of age with Atopic asthma:
The dosage for paediatric patients 6 to 14 years of age is one 5 mg chewable tablet daily to be taken at bedtime.
MACLUTEK chewable tablets have not been studied in seasonal allergic rhinitis in children with asthma.

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

Safety and efficacy for more than 12 (twelve) weeks has not been established in controlled clinical trials.

Therapy with **MACLUTEK** *in Relation to Other Treatments for Asthma:*
MACLUTEK can be added to a patient's existing treatment regimen.

Method of administration:
Oral use.
The tablets are to be chewed before swallowing.

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

4.4 Special warnings and precautions for use
General:
The efficacy of oral **MACLUTEK** for the treatment of acute asthma attacks has not been established.
MACLUTEK 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 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** can be continued during acute exacerbations of asthma.

While the dose of inhaled corticosteroid may be reduced gradually under medical supervision, **MACLUTEK** should not be abruptly substituted for inhaled or oral corticosteroids.
There are no data demonstrating that oral corticosteroid can be reduced when **MACLUTEK** 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 medicines while taking **MACLUTEK**. Although **MACLUTEK** 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.

Eosinophilic Conditions:
Patients on therapy with **MACLUTEK** 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** and these underlying conditions has not been established (see section 4.8)

Neuropsychiatric events
Neuropsychiatric events have been reported in adults, adolescents and children taking **MACLUTEK** (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** if such events occur.

Information for Patients
- Patients should be advised to take **MACLUTEK** 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** 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**, 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** 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 medicines while taking **MACLUTEK**.

MACLUTEK chewable tablets contain:
Aspartame, a source of phenylalanine. Patients with phenylketonuria should be informed that **MACLUTEK** contains aspartame) 1,2 mg per 4 mg chewable tablet, 1,5 mg per 5 mg chewable tablet.

4.5 Interaction with other medicines and other forms of interaction
MACLUTEK may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma, and seasonal allergic rhinitis. In drug-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** 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** 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 during pregnancy. A causal relationship between these events and MACLUTEK has not been established.

4.7 Effects on ability to drive and use machines
MACLUTEK 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**. 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 in all patient groups 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 diarrhoea, 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 Thirst
	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**.
There have been reports of acute overdosage in postmarketing experience and clinical studies with **MACLUTEK**. 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** 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). $CysLT_1$s 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.
Montelukast is an orally active compound which binds with high affinity and selectivity to the $CysLT_1$ 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_4 at the $CysLT_1$ 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 **4 mg chewable tablet**, C_{max} is achieved 2 hours after administration in paediatric patients 2 to 5 years of age in the fasted state.
Safety and efficacy were demonstrated in clinical studies where the 4 mg chewable tablet was administered without regard to the timing of food ingestion.

For the **5 mg chewable tablet**, the C_{max} is achieved 2 hours after administration in adults in the fasted state. The mean oral bioavailability is 73 %. Food does not have a clinically important influence with chronic administration.

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 metabolised 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
Elimination data are not available for children 2 to 5 years of age.
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 aspartame, cherry flavor, croscarmellose sodium, edetate disodium, ferric oxide red E172, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 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 or 60 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 medicine 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)
MACLUTEK 4 MG - 47/10.2.2/0597 and MACLUTEK 5 MG - 47/10.2.2/0598

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
28 FEBRUARY 2022

10. DATE OF REVISION OF THE TEXT
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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

MACLUTEK 4 mg (Chewable Tablets)
Montelukast 4 mg
Sugar free. Contains sweetener (aspartame 1,2 mg)

MACLUTEK 5 mg (Chewable Tablets)
Montelukast 5 mg
Sugar free. Contains sweetener (aspartame 1,5 mg)

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

1. What MACLUTEK is and what it is used for

MACLUTEK contains the active ingredient montelukast that is used for the treatment of asthma.
MACLUTEK 4 mg chewable tablets are used in children aged 2 to 5 years to treat asthma and prevent asthmatic symptoms.
MACLUTEK 5 mg chewable tablets are used in children aged over 6 years to treat asthma and prevent asthmatic symptoms.

You should take **MACLUTEK** as your doctor or healthcare provider told you as this may help reduce the severity of your child's asthma and the frequency of your child's asthma attacks. **MACLUTEK** blocks substances in your lungs called leukotrienes that cause narrowing and swelling (inflammation) of airways.

2. What you need to know before you take MACLUTEK

Do not take MACLUTEK
- If your child is allergic to montelukast or any of the other ingredients of **MACLUTEK.**

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

MACLUTEK chewable tablets are not for the treatment of acute asthma attacks. If an attack occurs, ensure your child follows the instructions your doctor has given your child for that situation.

Ensure your child has his/her emergency asthma pump or emergency medication for asthma attacks with them at all times.

It is important that your child takes all asthma medications prescribed for them by their doctor. **MACLUTEK** should not be used instead of other asthma medications the doctor has prescribed for your child.

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

If your child's 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.

If your child develops a combination of symptoms such as a flu-like illness (Pyrexia), paraesthesia / 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** (see section 4). If you develop such symptoms while taking **MACLUTEK**, you should consult your doctor.

Other medicines and MACLUTEK
Always tell your child's doctor, pharmacist or other healthcare professional your child is taking any other medicine. (This includes complementary or traditional medicines.)
The use of **MACLUTEK** 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 your child is taking the following medicines before starting **MACLUTEK:**
- 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 with food, drink and alcohol:
MACLUTEK 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** in pregnant and breastfeeding women has not been established.
It is not known if **MACLUTEK** is excreted in human milk.

Driving and using Machines
Dizziness and or drowsiness may occur in some patients taking **MACLUTEK.** You should not

Back Side

435 mm

360 mm

drive or operate machinery until you know how **MACLUTEK** affects you.

MACLUTEK contains aspartame
Phenylketonurics: Phenylketonuric patients should be advised that the chewable tablets contain phenylalanine (a component of aspartame as contained in **MACLUTEK**).

3. How to take MACLUTEK

- Do not share medicines prescribed for you with any other person.
- Always take **MACLUTEK** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how long your child's treatment with **MACLUTEK** will last. Do not stop giving **MACLUTEK** to your child early. If you have the impression that the effect of **MACLUTEK** is too strong or too weak for your child talk to your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **MACLUTEK**. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- Your child should take **MACLUTEK** once a day in the evening with or without food, as your doctor has told you.
- **The usual dose is:**
  MACLUTEK 4 mg chewable tablet:
  Children 2 to 5 Years with Atopic Asthma:
  The dosage for children 2 to 5 years of age is one 4 mg chewable tablet daily to be taken at bedtime.
  MACLUTEK 5 mg chewable tablet:
  Children 6 to 14 Years with Atopic Asthma:
  The dosage for children 6 to 14 years of age is one 5 mg chewable tablet daily to be taken at bedtime.
- The tablets are to be chewed before swallowing.

It is important that your child continues to take **MACLUTEK** for as long as your doctor prescribes it in order to maintain control of your child's asthma. **MACLUTEK** can treat your child's asthma only if you or your child continues to take it.

If your child takes more MACLUTEK than he/she 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 child's **MACLUTEK** to the hospital with your child.
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 give MACLUTEK to your child
Give **MACLUTEK** to your child as your doctor, pharmacist or other healthcare professional has told you. However, if your child misses a dose, take the usual schedule of one tablet once daily.
Do not give your child a double dose to make up for a forgotten dose.

If your child stops taking MACLUTEK
MACLUTEK can treat your child's asthma only if he/she continues taking it.
It is important for your child to continue taking **MACLUTEK** for as long as your doctor prescribes. It will help control your child's asthma.
If you have any further questions on the use of this medicine, ask your child's doctor or pharmacist.

4. Possible side effects

MACLUTEK can have side-effects.
Not all the side effects reported for this medicine are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking **MACLUTEK**, please consult your doctor, pharmacist or health care professional for advice.
If any of the following happens, stop giving **MACLUTEK** to your child 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 your child has them, he/she may have had a serious allergic reaction to **MACLUTEK**. Your child may need urgent medical attention or hospitalization.
Tell your doctor if your child develops 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), thirst.

Less frequent side effects
- Increased bleeding tendency, Low platelet level (thrombocytopenia) in your child's blood that can cause them to bleed.
- 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) and 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

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 contains

- The active substance is Montelukast sodium 4,16 mg and 5,2 mg equivalent to 4 mg and 5 mg of montelukast respectively.
- The other ingredients are aspartame, cherry flavor, croscarmellose sodium, edetate disodium, ferric oxide red E172, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose.

What MACLUTEK looks like and contents of the pack
MACLUTEK 4 mg chewable tablet:
Pink colour, oval, biconvex, uncoated chewable mottled tablet debossed with 'CL 55' on one side and plain on the other side.

MACLUTEK 5 mg chewable tablet:
Pink colour, mottled, circular, biconvex, uncoated chewable tablet debossed with 'CL 56' 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 or 60 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

28 FEBRUARY 2022

Registration number

MACLUTEK 4 MG - 47/10.2.2/0597 and MACLUTEK 5 MG - 47/10.2.2/0598

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 4 mg (Koubare Tablette)
Montelukast 4 mg
Suikervry. Bevat versoeter (aspartaam 1,2 mg)

MACLUTEK 5 mg (Koubare Tablette)
Montelukast 5 mg
Suikervry. Bevat versoeter (aspartaam 1,5 mg)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy MACLUTEK 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** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

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

1. Wat MACLUTEK is en waarvoor dit gebruik word

MACLUTEK bevat die aktiewe bestanddeel montelukast wat gebruik word vir die behandeling van asma.
MACLUTEK 4 mg koubare tablette word in kinders van 2 tot 5 jarige ouderdom gebruik vir die behandeling van asma en die voorkoming van asmatiese simptome.
MACLUTEK 5 mg koubare tablette word in kinders ouer as 6 jarige ouderdom gebruik vir die behandeling van asma en die voorkoming van asmatiese simptome.

Jy moet **MACLUTEK** neem soos jou dokter of gesondheidsorgverskaffer vir jou gesê het, aangesien dit kan help om die erns van jou kind se asma en die frekwensie van jou kind se asma-aanvalle te verminder.
MACLUTEK blokkeer stowwe in jou longe, naamlik leukotriene, wat vernouing en swelling (ontsteking) van lugweë veroorsaak.

2. Wat jy behoort te weet voordat jy MACLUTEK neem

Moet nie MACLUTEK neem nie
- Indien jou kind allergies is vir montelukast of enige van die ander bestanddele van **MACLUTEK**.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met **MACLUTEK**:
Indien jou kind se asmasimptome erger word, of indien jy jou kind se nood asma pompie of noodmedikasie vir asma-aanvalle meer dikwels moet gebruik, moet jy onmiddellik jou dokter kontak.

MACLUTEK koubare tablette is nie vir die behandeling van akute asma-aanvalle nie. Indien daar 'n aanval plaasvind, maak seker dat jou kind die instruksies volg wat jou dokter vir daardie situasie gegee het.

Maak seker dat jou kind te alle tye sy/haar nood asma pompie of noodmedikasie vir asma-aanvalle by hulle het.

Dit is belangrik dat jou kind al die asma medikasie wat deur hul dokter vir hulle voorgeskryf is, inoet neem. **MACLUTEK** moet nie gebruik word in die plek van ander asma medikasie wat die dokter vir jou kind voorgeskryf het nie.
Indien jou dokter 'n medisyne vir jou kind voorgeskryf het wat voor oefening moet gebruik word, moet jou kind daardie medisyne aanhou gebruik.

Indien dit bekend is dat jou kind se esma 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.

Wanneer jou kind 'n kombinasie van simptome ontwikkel, soos 'n griepagtige siekte (Pireksie) droggevoel/hipoëstesie, verergering van longsimptome en/of uitslag, moet jy jou dokter raadpleeg.

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

Ander medisyne en MACLUTEK
Vertel altyd vir jou kind se dokter, apteker of ander professionele gesondheidsorgwerker indien jou kind enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Die gebruik van **MACLUTEK** saam met ander medisyne kan ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies as jy onseker is.
Dit is veral belangrik dat jy jou dokter moet vertel indien jou kind die volgende medisyne neem voordat hy/sy met **MACLUTEK** begin word:
- fenobarbitoon (gebruik vir die behandeling van epilepsie)
- fenitoïen (gebruik vir die behandeling van epilepsie)
- rifampisien (gebruik om tuberkulose en sommige ander infeksies te behandel).
- gemfibrosil (gebruik vir hoë vetvlakke in jou bloed (cholesterol)).

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

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy 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** in swanger en borsvoedende vrouens is nie vasgestel nie.
Dit is nie bekend of **MACLUTEK** in menslike melk uitgeskei word nie.

Bestuur en gebruik van masjiene
Duiseligheid en/of lomerigheid kan voorkom in sommige pasiënte wat **MACLUTEK** neem. Jy moet nie bestuur of masjinerie beheer totdat jy weet hoe **MACLUTEK** jou affekteer nie.

MACLUTEK bevat aspartaam
Fenielketonurie: Fenielketonuriese pasiënte moet ingelig word dat die koubare tablette fenielalanien bevat ('n komponent van aspartaam soos vervat in **MACLUTEK**).

3. Hoe om MACLUTEK te gebruik

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
- Gebruik altyd **MACLUTEK** presies soos jou dokter of apteker jou beveel het. Raadpleeg jou dokter of apteker as jy nie seker is nie.
- Jou dokter sal vir jou sê hoe lank jou kind se behandeling met **MACLUTEK** sal duur. Moet nie vroeër ophou om **MACLUTEK** vir jou kind te gee nie. Praat met jou dokter of apteker, indien jy onder die indruk is dat die effek van **MACLUTEK** te sterk of te swak is vir jou kind.
- Bly onder 'n gesondheidsorgverskaffer se sorg wanneer jy **MACLUTEK** neem. Moet nie jou behandeling verander of jou behandeling staak sonder om eers met jou gesondheidsorgverskaffer te praat nie.
- Jou kind moet **MACLUTEK** een keer per dag in die aand met of sonder kos neem, soos jou dokter vir jou gesê het.
- **Die gewone dosis is:**
  MACLUTEK 4 mg koubare tablet
  Kinders 2 tot 5 jaar oud met Atopiese Asma:
  Die dosis vir kinders 2 tot 5 jarige ouderdom is een 4 mg koubare tablet daagliks om voor slaaptyd geneem te word.
  MACLUTEK 5 mg koubare tablet
  Kinders 6 tot 14 jaar oud met Atopiese Asma:
  Die dosis vir kinders 6 tot 14 jarige ouderdom is een 5 mg koubare tablet daagliks om voor slaaptyd geneem te word.
- Die tablette moet gekou word voordat dit ingesluk word.

Dit is belangrik dat jou kind aanhou om **MACLUTEK** te gebruik vir so lank as wat jou dokter dit voorskryf ten einde beheer oor jou kind se asma te behou. **MACLUTEK** kan slegs jou kind se asma behandel indien jy of jou kind aanhou om dit te neem.

Indien jou kind meer MACLUTEK neem as wat hy/sy 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 giftbeheersentrum en neem jou kind se **MACLUTEK** saam met jou kind na die hospitaal toe.
Die mees algemene simptome wat met oordosering in volwassenes en kinders aangemeld is, was onder meer abdominale pyn, slaperigheid, dors, hoofpyn, braking en hiperaktiwiteit.

Indien jy vergeet om MACLUTEK vir jou kind te gee
Gee **MACLUTEK** vir jou kind soos jou dokter, apteker of ander professionele gesondheidsorgwerker vir jou gesê het. Indien jou kind egter 'n dosis oorslaan, gaan net met die gewone skedule van een tablet een keer per dag aan. Moet nie vir jou kind 'n dubbele dosis gee om op te maak vir die vergete dosis nie.

Indien jou kind ophou om MACLUTEK te neem
MACLUTEK kan slegs jou kind se asma behandel as hy/sy dit aanhou neem.
Dit is belangrik dat jou kind voortgaan om **MACLUTEK** te neem vir so lank as wat jou dokter dit voorskryf. Dit sal help om jou kind se asma te beheer.
Indien jy enige verdere vrae oor die gebruik van hierdie medisyne het, vra jou kind se dokter of apteker.

4. Moontlike newe-effekte

MACLUTEK kan newe-effekte hê.
Nie al die newe-effekte wat vir **MACLUTEK** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou kind se algemene gesondheid verslag of jou kind enige ongewenste effekte ondervind terwyl hulle **MACLUTEK** gebruik, raadpleeg asseblief jou dokter, apteker of professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **MACLUTEK** vir jou kind te gee en vertel onmiddellik 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.

Hierdie is almal baie ernstige newe-effekte. Indien jou kind dit het, mag hy/sy 'n ernstige allergiese reaksie op **MACLUTEK** gehad het. Jou kind mag dringende mediese aandag of hospitalisasie nodig hê.
Vertel jou dokter wanneer jou kind 'n kombinasie van simptome ontwikkel soos
- 'n Griepagtige siekte (Pireksie).
- Tipiese tintaling of prikkeling/spelde en naalde (Parestesie).
- Gevoelloosheid in 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 as jy enige van die volgende newe-effekte opmerk:
Gereelde newe-effekte:
- Boonste lugwegeffekte.
- Hoofpyn
- Abdominale pyn, diarree, 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), dors.

Minder gereelde newe-effekte:
- Verhoogde bloedingsneiging, lae bloedplaatjievlak (trombositopenie) in jou kind se bloed wat kan veroorsaak dat hulle bloei.
- Abnormale drome, insluitend nagmerries, probleme om aan die slaap te raak en om aan die slaap te bly (slapeloosheid), slaapwandeling (somnambulisme), bekommerde gevoel (angs), agitasie, insluitend aggressiewe gedrag of vyandigheid, depressie, psigomotoriese hiperaktiwiteit (insluitend prikkelbaarheid, rusteloosheid, bewing), aandagverswakking , geheue inkorting, senutrekking, hallusinasies, disoriëntasie, selfmoordgedagtes en gedrag (selfmoord), obsessief-kompulsiewe simptome, warspraak.
- Duiseligheid, lomerigheid, slaperigheid, tintaling of prikkeling/spelde en naalde (parestesie), gebrek aan gevoel (hipoëstesie), aanvalle.
- Vinnige, sterk of onreëlmatige hartklop (Palpitasies)
- Neusbloeding (Epistaksie), inflammasie van bloedvate (Churg-Strauss sindroom), pulmonêre eosinofilie.
- Droë mond, slegte spysvertering.
- Hepatitis (insluitend cholestatiese, hepatoselulêre en gemengde patroon lewerbeserking).
- Kneusing, galbulte (urtikarie), pruritus, pynlose swelling onder die vel (angioëdeem), teer rooiknoppe onder die vel mees algemeen op jou skeenbeen (knobbelhuidrooiheid) 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).

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

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/Publication/Index/8.

5. Hoe om MACLUTEK 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 bevat
- Die aktiewe bestanddeel is montelukast natrium 4,16 mg en 5,2 mg gelykstaande aan onderskeidelik 4 mg en 5 mg montelukast.
- Die ander bestanddele is aspartaam, kersiegeursel, natriumkruiskarmellose, dinatriumedetaat, rooi ysteroksied E172, hidroksipropielsellulose, magnesiumstearaat, mannitol, mikrokristallyne sellulose.

Hoe MACLUTEK lyk en inhoud van die pak
MACLUTEK 4 mg koubare tablet:
Pienk kleurige, ovaal, bikonveks, onbedekte koubare gevlekte tablet met 'CL 55' op die een kant gedruk en glad aan die ander kant.

MACLUTEK 5 mg koubare tablet:
Pienk kleurige, gevlekte, sirkelvormige, bikonvekse, onbedekte koubare tablet met 'CL 56' op die een kant gedruk 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 hittesêllak 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 of 60 ml HDPE-houer met 33-400 mm nekafwerking wat toegemaak is met 33 mm kinderbestande sluiting met pulp en hittesêlvoering en word verpak in 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

28 Februarie 2022

Registrasienommer

MACLUTEK 4 mg CHEWABLE TABLETS: 47/10.2.2/0597
MACLUTEK 5 mg CHEWABLE TABLETS: 47/10.2.2/0598

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.

MASTER COPY

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

~~(Front Page)~~

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: MACLUTEK 4/5 mg CHEWABLE TABLETS (Montelukast 4/5 mg chewable 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.: PM03843901
11. Artwork has been made: Actual Size	12. Pharma code No.: 31489 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 4/5 mg PI & PIL-PM03843901.cd
Approved By:	17. Location: Baddi

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

QA 03/09/22

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03843901		

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