Module 1.3.2: Approved Patient Information Leaflet

for the Patient about

MEFLIAM (TABLETS)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MEFLIAM containing **mefloquine** 250 mg (Tablets)

Read all of this leaflet carefully before you start taking MEFLIAM:

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **MEFLIAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them.**

WHAT MEFLIAM CONTAINS:

The active ingredient in **MEFLIAM** is mefloquine.

Each tablet contains mefloquine hydrochloride equivalent to mefloquine 250 mg.

Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, polysorbate 80, povidone, starch, and talc.

Contains lactose monohydrate: 193 mg per tablet.

WHAT MEFLIAM IS USED FOR:

MEFLIAM is used for the prevention of malaria in regions where the malaria parasite is resistant (not sensitive) to other anti-malaria medicines. Your doctor will decide whether you qualify for preventative therapy with **MEFLIAM**.

BEFORE YOU TAKE MEFLIAM:

Do NOT take MEFLIAM / Do NOT administer MEFLIAM to your child:

- If you or your child is allergic (hypersensitive) to mefloquine or related compounds (e.g. quinine and quinidine) or any of the inactive substances contained in **MEFLIAM**.
- If you or your child has been diagnosed with depression, or previously had depression, or if you or your child has generalised anxiety disorder, schizophrenia or other psychiatric disturbances (see **"Take special care with MEFLIAM"**).
- If you or your child has previously suffered a convulsion (seizure) (see **"Take special care with MEFLIAM"**).
- Your child weighs less than 5 kg.
- If you or your child has been diagnosed with impaired kidney or liver function, since safety has not been demonstrated.
- If you are pregnant (see **"Pregnancy and breastfeeding"**).
- If you are breastfeeding your baby (see **"Pregnancy and breastfeeding"**).

Take special care with MEFLIAM:

MEFLIAM may cause psychiatric symptoms in some people (see **"POSSIBLE SIDE EFFECTS"**). Please report to your doctor as soon as possible if you or your child

experiences anxiety, paranoia (excessive or irrational suspiciousness and distrustfulness of others) or depression. Please report to your doctor immediately if you or your child hears or sees things that are not real. You may continue to experience these symptoms for some time after treatment with **MEFLIAM** has been stopped. You should also report to your doctor if you or your child contemplates suicide or frequently thinks about death. To minimise the chances of these adverse events, please inform your doctor if you or your child has depression, generalised anxiety disorder, schizophrenia, or other psychiatric disturbances (see **"Do NOT take MEFLIAM"**).

If you or your child experiences unexplained anxiety, depression, restlessness or confusion during **MEFLIAM** preventative therapy, stop taking **MEFLIAM** and report to your doctor for alternative preventative treatment, as these symptoms may become worse.

MEFLIAM may cause allergic reactions, which may range from mild skin conditions to severe allergic reactions characterised by swelling of lips, tongue or throat, troubled breathing, tightness of the chest or shortness of breath, blisters on the skin, ulcers in the mouth or on the lips, hives, itching, or fever. If you or your child develops any of the above symptoms, or any other symptom you think may be due to an allergic reaction, you or your child must immediately stop taking **MEFLIAM** and you must inform your doctor immediately (see **"Do NOT take MEFLIAM"** and **"POSSIBLE SIDE EFFECTS"**).

MEFLIAM may increase the risk of convulsions/seizures (see "Do NOT take MEFLIAM" and "Taking other medicines with MEFLIAM") in people with epilepsy. Please inform your doctor if you or your child has been diagnosed with epilepsy before starting preventative therapy with MEFLIAM.

Be sure to inform your doctor if you or your child has been diagnosed with a heart condition or heart rhythm disorder, since MEFLIAM may slow your heart rate or cause abnormal heart rhythms. Your doctor may want to consider alternative treatment options.

Please inform your doctor if you or your child is currently taking quinine, chloroquine or halofantrine for malaria prevention or quinidine for heart rhythm abnormalities, as concomitant use with **MEFLIAM** may produce heartbeat abnormalities and increase the risk of convulsions/seizures (see **"Do NOT take MEFLIAM"** and **"Taking other medicines with MEFLIAM"**).

MEFLIAM may increase the risk of eye/vision problems, including clouding of the lens of the eye causing blurred vision, or loss of vision or colour vision, which may occur while you are taking **MEFLIAM**, or after you have finished taking **MEFLIAM** (see **"POSSIBLE SIDE EFFECTS"**). In some people such vision problems resolved very slowly, however, there have been reports of permanent eye or vision problems.

Report to your treating doctor if you or your child experience blurred vision or any other problems with your vision while you or your child are taking **MEFLIAM**, or after you have finished taking **MEFLIAM**, as your doctor may decide to stop treatment

with **MEFLIAM** and prescribe alternative malaria preventative treatment.

You or your child will have to go for regular check-ups with your doctor (including blood tests to monitor your liver function and eye examinations) if you have to continue with **MEFLIAM** preventative therapy for longer than 3 months.

Immediately stop taking **MEFLIAM** and report to your doctor if you or your child develops altered mental status (including reduced consciousness), memory loss, or visual problems.

If you or your child develops flu-like symptoms after you have been to a malaria area, you should inform your doctor immediately.

If you or your child is known with poor liver function or liver disease, you are at higher risk of developing side effects (see **"Do NOT take MEFLIAM"**). Please discuss the use of **MEFLIAM** with your treating doctor.

Please inform your doctor if you or your child is known with poor kidney function (see **"Do NOT take MEFLIAM"**).

Because **MEFLIAM** is broken down very slowly and remains in the body for an extended period of time, **MEFLIAM** side effects may occur or persist up to several weeks after the last dose (see **"POSSIBLE SIDE EFFECTS"**).

Additional preventative measures:

Even though you or your child is taking **MEFLIAM** to prevent malaria, it remains very important that you employ the following measures to prevent mosquitoes from biting you or your child to further reduce the risk of contracting malaria:

- Visit malarial areas during the dry season or in years when rainfall is low.
- Do not go outside between dusk and dawn, when mosquitoes are most active.
- Apply insect repellent to exposed skin and clothes.
- Wear long sleeves and long trousers at night.
- Use mosquito nets, screens, coils and pads.

The following people should avoid visiting malaria areas altogether:

- Babies and children younger than 5 years of age.
- Pregnant women.
- People whose immune systems are not functioning optimally, such as people taking long-term steroids, cancer patients, patients receiving chemotherapy, AIDS patients and people who have had their spleen removed.

Taking MEFLIAM with food and drink:

Swallow **MEFLIAM** tablets whole after food with plenty of fluids (see **"HOW TO TAKE MEFLIAM"**). You may crush **MEFLIAM** tablets and suspend it in a small amount of water, milk or other beverage for small children and other people unable to swallow the tablet whole. **MEFLIAM** has a bitter and slightly burning taste.

Pregnancy and breastfeeding:

Do not take **MEFLIAM** if you are pregnant (see **"Do NOT take MEFLIAM"**). If you are a woman of childbearing age, you should use reliable contraception during malaria preventative therapy with **MEFLIAM** and for up to 3 months thereafter.

Do not take **MEFLIAM** if you are breastfeeding your baby (see **"Do NOT take MEFLIAM"**), since **MEFLIAM** is excreted in breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MEFLIAM.

Driving and using machinery:

You must exercise caution while driving, piloting aircraft, scuba diving, mountain climbing, hiking and biking and operating machines as you may experience dizziness, disturbed sense of balance or unexplained anxiety, depression, restlessness or confusion while taking **MEFLIAM** and for three weeks afterwards (see **"POSSIBLE SIDE EFFECTS"**). You should refrain from performing any of the above tasks until you know how **MEFLIAM** affects you.

Important information about some of the ingredients in MEFLIAM:

MEFLIAM contains lactose. If you or your child suffers from hereditary galactose intolerance, glucose-galactose malabsorption, or the Lapp lactase deficiency, do not take **MEFLIAM**. Please discuss this with your doctor if you are unsure.

Taking other medicines with MEFLIAM:

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

Please inform your doctor if you or your child is taking any of the following medicines, since taking **MEFLIAM** in combination with any of these medicines may slow your heart rate, cause abnormal heart rhythms or lead to cardiac arrest:

- Beta-blockers, such as bisoprolol, atenolol or propranolol, for heart rhythm disorders or high blood pressure.
- Calcium channel blockers, such as diltiazem, felodipine, isradipine, verapamil or nifedipine, for high blood pressure, heart rhythm disorders, or angina.
- Antihistamines to relieve allergies or skin rashes.
- Tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine or promethazine, for depression or anxiety.
- Phenothiazines, such as chlorpromazine, pimozide or prochlorperazine, for schizophrenia or bipolar disorder.
- Quinidine for abnormal heart rhythms (see **"Take special care with MEFLIAM"**).
- Quinine for malaria (see **"Take special care with MEFLIAM"**).
- Halofantrine for malaria.

Taking **MEFLIAM** in combination with quinine, quinidine or chloroquine may increase the risk of developing seizures (convulsions) (see **"Take special care with MEFLIAM"**).

If your doctor has prescribed **MEFLIAM** in combination with anti-epileptic medicines, e.g. valproic acid, carbamazepine, phenobarbital or phenytoin, you will have to go for blood tests to monitor the blood levels of these medicines. Your doctor may have to adjust the dosage of your anti-epileptic medicines (see **"Take special care with MEFLIAM"**).

If the oral typhoid vaccine has been prescribed for you or your child, remember that you must separate the doses of the two medicines by 7 to 10 days. The oral typhoid vaccine must be taken 7 to 10 days before the first **MEFLIAM** tablet is taken. Remember that the first dose of **MEFLIAM** should be taken at least one week before entering the malarial area. Please ask your doctor or pharmacist to assist you with an appropriate dosing schedule.

Please inform your doctor if you are taking warfarin (a blood thinner) or antidiabetic medicines (such as metformin, glimepiride, glipizide or pioglitazone) before you start taking **MEFLIAM**. Your doctor may want to perform blood tests to check your prothrombin time / INR (International Normalised Ratio) or blood sugar levels before you visit the malarial area.

HOW TO TAKE MEFLIAM:

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

Always take MEFLIAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose for adults and children weighing more than 45 kg is 1 tablet (250 mg) once weekly. If your child weighs 45 kg or less, your doctor will calculate the appropriate dose based on body weight. **MEFLIAM** should not be given to children weighing less than 5 kg or to infants younger than 3 months.

MEFLIAM tablets should be swallowed whole after food with plenty of fluids. The tablets may be crushed and suspended in a small amount of water, milk or other beverage for administration to small children and other persons unable to swallow them whole. **MEFLIAM** has a bitter and slightly burning taste.

You should take the first **MEFLIAM** dose one week before arrival in the malarial area and the following once-weekly doses should be taken on the same day of each week. In certain instances, e.g. if you are taking other medicines, your doctor may instruct you to start **MEFLIAM** preventative treatment 2 – 3 weeks prior to departure in order to ensure that your combination of medicines is well tolerated.

MEFLIAM preventative treatment should be continued for four weeks after leaving the malarial area. Your doctor will tell you how long treatment with **MEFLIAM** should last. Do not stop taking **MEFLIAM** before you are instructed to do so, as you will increase your risk of contracting malaria.

If you have the impression that the effect of **MEFLIAM** is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more MEFLIAM than you should:

If you take more **MEFLIAM** than you should, you may experience any of the side effects listed below (see **"POSSIBLE SIDE EFFECTS"**). **In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

If you forget to take MEFLIAM:

Always take **MEFLIAM** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE EFFECTS:

MEFLIAM can have side effects.

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

Serious side effects that you should report to your doctor immediately include:

- Those that occur less frequently:
    - Swelling of the lips, tongue, or throat, which cause difficulty in breathing and swallowing.
    - Hearing or seeing things that are not real (see **"Take special care with MEFLIAM"**).

    - Thoughts about suicide or death (see **"Take special care with MEFLIAM"**).
    - Altered mental status, confusion or loss of body function.
    - Slow heart rate or irregular heart rhythm.
    - Skin rashes, especially skin rashes with blister formation (see **"Take special care with MEFLIAM"**).
- Those that occur with unknown frequency:
    - Fever, chills, coughing, sore throat, ulcers that will not heal, pain in the flank or blood in the urine, shortness of breath, pin point red spots on the skin, easy bruising or bleeding from the gums, as this may be due to low blood cell or platelet counts.
    - Aggression, emotional instability, or panic attacks (see **"Take special care with MEFLIAM"**).
    - Struggling to keep your balance, abnormal gait, or tremor.
    - Seizures (convulsions) (see **"Take special care with MEFLIAM"**).
    - Palpitations, chest pain, rapid heart rate, or sudden collapse.

Side effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
    - Problems with your vision, such as blurred vision (see **"Take special care with MEFLIAM"**).
- Those that occur less frequently:
    - Anxiety, confusion, depression (see **"Take special care with MEFLIAM"**).
- Those that occur with unknown frequency:

    - Pins and needles.
    - Visual disturbances, clouding of the lens of the eye causing blurred vision (cataract), loss of vision or loss of colour vision (colours appearing faded or washed out), which may occur while you or your child are taking **MEFLIAM**, or after you have finished taking **MEFLIAM** (see **"Take special care with MEFLIAM"**).
    - Hearing impairment.
    - High blood pressure, swelling.
    - Itching, hives.

Side effects that you should report to your doctor if they continue or become bothersome include:

- Those that occur frequently:
    - Emotional problems.
    - Headache.
    - Dizziness, ringing in the ears.
    - Stomach pain, loose stools (diarrhoea), nausea, vomiting.
    - Muscle pain and/or joint pain.
    - Fever, chills.
- Those that occur less frequently:
    - Sleep disturbances, such as abnormal dreams and sleeplessness.
    - Feeling of weakness.
    - Loss of appetite.
    - Hair loss.
- Those that occur with unknown frequency:

- Sleepiness.
- Low blood pressure.
- Flushing of the skin.
- Indigestion.
- Redness, lumps on the skin, sweating.
- Muscle cramps or weakness.
- Fatigue, general feeling of discomfort or illness.

Adverse events can be observed several weeks after the last dose has been taken.

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

STORING AND DISPOSING OF MEFLIAM:

Store at or below 25 ºC.

Protect from moisture.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF MEFLIAM:

MEFLIAM tablets are available in blister packs of 6 and 8 tablets.

IDENTIFICATION OF MEFLIAM:

Flat, white, circular uncoated tablets with bevelled edges. One side has a cross breakline and the other side is plain.

REGISTRATION NUMBER:

31/20.2.6/0502

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Parc du Cap

Mispel Street

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