SCHEDULING STATUS

S2

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM

Mozitec Film-coated Tablets

Atovaquone 250 mg and Proguanil Hydrochloride 100 mg

Read all of this leaflet carefully before you start taking **Mozitec**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Mozitec** 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.

1. WHAT MOZITEC TABLETS CONTAIN

The active substances in each **Mozitec** tablet are 250 mg atovaquone and 100 mg proguanil hydrochloride.

The other (inactive) ingredients are microcrystalline cellulose (Avicel PH 101), low substituted hydroxypropyl cellulose (L-HPC LH-21), sodium starch glycolate (Primojel), poloxamer 188 (Lutrol F68), povidone (Kollidon 30), microcrystalline cellulose (Avicel PH 102), colloidal silicone dioxide (Aerosil 200), magnesium stearate, opadry brown 03C86943 and purified water.

2. WHAT MOZITEC TABLETS ARE USED FOR

Mozitec is indicated for the prevention of *Plasmodium falciparum malaria.* It belongs to a group of medicines called antimalarials.

Mozitec is used to reduce the risk of contracting malaria caused by *Plasmodium falciparum*, a parasite. **Mozitec** contains two active ingredients which kill the malaria parasites in your body to reduce the risk of contracting malaria.

3. BEFORE YOU TAKE MOZITEC TABLETS

Do not take **Mozitec** tablets:

- If you are allergic to atovaquine, proguanil or any of the other ingredients of **Mozitec**.
- If you have severe kidney impairment.

Tell your doctor or health care professional before taking Mozitec if:

- you weigh less than 40 kilograms
- you have diarrhoea or are vomiting
- you are taking any medicines containing rifampicin, rifabutin, tetracycline or metoclopramide
- you are taking medicine containing indinavir
- you have problems with your kidneys.
- you are pregnant or likely to become pregnant soon
- you are breastfeeding

Taking Mozitec Tablets with food and drink

- **Mozitec** tablets should be taken with food or milk.

Pregnancy and Breastfeeding

Before taking **Mozitec**, tell your doctor if you are breastfeeding, pregnant or likely to become pregnant soon.

If you are pregnant or breastfeeding your baby while taking **Mozitec**, please consult your doctor, pharmacist or other health care professional for advice.

Safety during pregnancy and breastfeeding has not been established. Women breastfeeding their infants should not receive **Mozitec**.

Driving and using machinery

No studies have been done to investigate the effect of **Mozitec** on driving performance or the ability to operate machinery.

Taking other medicines with Mozitec tablets:

If you are using medicines on a regular basis, including complementary or traditional medicines, the use of **Mozitec** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professionals for advice.
Make sure your doctor knows what other medicines you are taking, including those that you have bought yourself.

Before taking **Mozitec**, tell you doctor if:

- you are taking any medicines containing rifampicin, rifabutin, tetracycline or metoclopramide
- you are taking medicine containing indinavir

4. HOW TO TAKE MOZITEC TABLETS:

Do not share medicines prescribed for you with any other person
Always take **Mozitec** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Prevention of malaria:

The usual dose is:

Adults: One **Mozitec** tablet daily.

In order to prevent malaria, it is important that you take your **Mozitec** every day. Start taking 1 or 2 days before travelling to an area, or a country (or countries) where malaria is transmitted, continue daily dosing while you are there, and for 7 days after returning. **Mozitec** tablets should be swallowed whole with a drink. Take the tablets with food or milk, as the active ingredients are then absorbed better from the stomach.

For prevention of malaria **Mozitec** should be taken at the same time each day. In the event of vomiting within one hour of taking a dose, a repeat dose should be taken. In the event of diarrhoea, normal dosing should be continued and personal protection should be used (repellents, bed nets). Your doctor may decide to give you other medicines as well**.** Please read any instruction leaflet carefully.

Your doctor will tell you how long your treatment with **Mozitec** will last. Do not stop treatment because you may increase the risk of contracting malaria. If you have the impression that the effect of **Mozitec** is too strong or too week, tell your doctor or pharmacist.

If you take more Mozitec tablets than you should:

It is important to take only the dose of **Mozitec** prescribed by your doctor.

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

If you forget to take Mozitec tablets:

If you forget to take a dose, take another as soon as possible. Then go on as before.

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

5. POSSIBLE SIDE EFFECTS:

Mozitec can have side effects.

Not all side-effects reported for **Mozitec** are included in this leaflet. Should your general health worsen while taking **Mozitec**, please consult your doctor, pharmacist or other health care professionals for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- rash or itching,

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **Mozitec**. You may need urgent medical attention or hospitalisation. All of these very serious side effects usually occur less frequently.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever

This is a serious side effect. You may need urgent medical attention. Serious side effects usually occur less frequently.

Tell your doctor as soon as possible, if you notice any of the following:

- Loss of appetite, feeling sick (nausea) and/or being sick (vomiting), stomach pain, diarrhoea.
- Mouth inflammation (swelling, redness, pain) and mouth ulcers.
- Allergic reactions including rash, itching and swelling.
- Headache, difficulty in sleeping, raised body temperature, hair loss, cough.

Mozitec may cause changes to the body's normal blood levels of certain cells or chemicals or lead to other blood abnormalities. If you are having a blood test for any reason, tell the person who is taking your blood sample that you are receiving **Mozitec,** as it may affect your result. While taking **Mozitec,** if you feel unwell or have any unusual symptoms, even those that are not mentioned in this leaflet, seek the advice of your doctor or pharmacist.

6. STORING AND DISPOSING OF MOZITEC TABLETS:

Store at or below 25 °C.

Do not use **Mozitec** tablets after the expiry date shown on the pack.

Do not share medicines prescribed for you with others.

Keep all medicines out of the reach and sight of children. It may harm them.

7. PRESENTATION OF MOZITEC TABLETS:

Mozitec tablets are packed in white HDPE containers with white caps containing 100 tablets.

Mozitec Tablets are packed in PVC/PVDC (Clear) film backed with push through Aluminium foil blister containing 12 tablets.

8. IDENTIFICATION OF MOZITEC TABLETS:

Mozitec tablets: Pinkish brown to brown coloured, circular, biconvex bevelled edge film-coated tablets with '404' debossed on one side and 'G' debossed on the other side.

9. REGISTRATION NUMBER:

47/20.2.6/1014

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Activo Health (Pty) Ltd

Block B, Arena Office Park

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0157

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