

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[MA166 trade name][†]
Pyrimethamine/sulfadoxine

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly .*

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours..
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [MA166 trade name] is and what it is used for
2. What you need to know before you take [MA166 trade name]
3. How to take [MA166 trade name]
4. Possible side effects
5. How to store [MA166 trade name]
6. Contents of the pack and other information

1. What [MA166 trade name] is and what it is used for

[MA166 trade name] contains two medicines: pyrimethamine and sulfadoxine, used to prevent malaria in children aged less than 12 months and during pregnancy (intermittent preventive treatment of malaria). The health care provider will use the most recent official guidelines on the use of malaria medicines to check that the medicine is the right one and on when to start giving it to you or to your child.

2. What you need to know before you take [MA166 trade name]

Do not take or give [MA166 trade name]:

- if you or your child are allergic (hypersensitive) to pyrimethamine, sulfadoxine (or another sulfonamide) or to any of the other ingredients of [MA166 trade name] (see section 6 What [MA166 trade name] contains).
- if your child is premature or during his/her first 2 months of life
- if you or your child ever suffered blood disorders with pyrimethamine or sulfadoxine.

If you are not sure you or your child should be given [MA166 trade name], talk to your health care provider before taking this medicine or giving it to your child.

Warnings and precautions

Check with your health care provider before taking [MA166 trade name] or giving it to your child:

- if you or your child are suffering from a recent illness. Malaria may need to be treated with a different medicine
- if you or your child have been treated in the past 30 days with medicines containing pyrimethamine and sulfadoxine

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- if you or your child are HIV-positive and you or he/she have been taking a combination of sulfamethoxazole and trimethoprim because this increases side effects.

If any of the above applies to you or your child, or if you are not sure, talk to your health care provider before you take [MA166 trade name] or give it to your child.

If you or your child get a skin rash or itchiness with [MA166 trade name], stop taking [MA166 trade name] or giving it to your child and talk to your health care provider.

Taking other medicines

Tell your health care provider about any other medicine that you or your child are taking or have recently taken. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your health care provider if you or your child are taking any of the following medicines:

- malaria medicines containing pyrimethamine or sulfadoxine
- medicines containing sulfamethoxazole and trimethoprim (for preventing certain infections in people who are HIV positive)
- antibacterial medicine which contains a sulfonamide

Pregnancy and breastfeeding

[MA166 trade name] should not be used during the first trimester of pregnancy. During the 2nd or 3rd trimesters of pregnancy, [MA166 trade name] may be used for intermittent preventive treatment in pregnancy. [MA166 trade name] can be used during breastfeeding.

Driving and using machines

Side effects are not expected to affect attention or reduce co-ordination but patients receiving [MA166 trade name] should be warned that undesirable effects such as dizziness may occur, in which case they should not drive or use machines.

Other ingredients of [MA166 trade name]

[MA166 trade name] contains small amounts of lactose and sucrose (from the orange flavour). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take [MA166 trade name]

Your health care provider will tell you when to start treatment with [MA166 trade name].

Children

Treatment is given 3 times during the first year of life at approximately 10 weeks, 14 weeks, and 9 months of age, at the time when your child is also given their routine vaccinations.

The correct dosage of [MA166 trade name] depends on the weight of your child.

If your child weighs 5 kg or more, they will be given 1 tablet of [MA166 trade name].

Children weighing less than 5 kg are given half a tablet.

Pregnancy

For treatment to protect against malaria during pregnancy, your health care provider will normally use a stronger formulation. If you have to be given [MA166 trade name] instead, the dose is 6 tablets, which corresponds to 1500 mg of sulfadoxine and 75 mg of pyrimethamine.

Doses should be given at each planned visit to your health care provider, from the beginning of the second trimester of your pregnancy until delivery. The doses of [MA166 trade name] are given at least one month apart.

Method of administration

[MA166 trade name] is a tablet to be dispersed in drinking water and swallowed. It can be given either on an empty stomach or with food.

Your health care provider will prepare the medicine and give it to you or your child.

Missing a dose reduces protection but does not prevent receiving the next dose.

Instructions for use

For **adults**, the following procedure should be used.

- Around 50 mL of clean drinking water should be taken in a small and clean cup or glass and the tablets added.
- The container should be gently swirled until tablets disperse, and all of the mixture should be drunk straight away.
- The container is rinsed with an additional 10 mL of water, which you should drink to ensure the whole dose is taken.

For use in **infants**:

- The tablet should be divided into half along the break line if necessary.
- Around 10 mL of clean drinking water should be taken in a small and clean cup or glass, and the appropriate dose added.
- The cup should be gently swirled until the tablet disperses and the entire mixture is given to the child to drink straight away.
- The container should be rinsed with an additional 5-10 mL of water, and given to the child to drink to ensure the whole dose is taken.

If your child vomits the dose within 30 minutes, they should be allowed to rest for 30 minutes and then be given a second dose. If they vomit a second time, no further dose should be attempted.

If you have any questions on the use of this medicine, ask your health care provider.

If you or child take more [MA166 trade name] than you should

If you or your child have taken too much [MA166 trade name], tell your health care provider.

If you forget to take [MA166 trade name] or to give it to your child at the right time

You or your child should take the medicines at the right time to have the best chance of preventing malaria. Missing a dose reduces protection but you or your child can still receive the next dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

Pyrimethamine/sulfadoxine can cause skin rash and side effects on moist areas such as the lining of the nose and the mouth.

Serious but rare side effects include blood disorder, liver damage and severe skin reactions.

Other side effects have occurred with pyrimethamine/sulfadoxine usually in adults treated for malaria but not when these medicines are used for intermittent preventive treatment of malaria in children and during pregnancy. These side effects include:

General disorders

fever, chills, lupus-like effects (joint pain and stiffness, swollen glands and skin rashes), swelling of blood vessels to the gut, kidneys and nerves.

Mental and nervous system disorders:

Depression, apathy, nerve disorders, fits, inability to move properly, sleeplessness, muscle weakness, hallucinations

Digestive system

Feeling sick, inflammation of the tongue and in the mouth, stomach feeling full

Liver and pancreas

Inflammation of the pancreas and blood test showing a temporary increase in liver enzymes

Skin

Serious reactions with flu-like symptoms and blistering rashes, skin reactions caused by sunlight, slight hair loss, hives, itching, inflammatory skin rash.

Eyes

Temporary problems with focussing, clouding of the clear layer at the front of the eye (which gets better when the medicine is stopped), damage to the light-sensitive layer at the back of the eye, swelling around the eyes, and redness

Ear

ringing or buzzing sound in the ear, sense of losing balance or feeling giddy

Heart

Inflammation of the heart and of the sac that surrounds the heart

Blood sugar and kidneys

Kidney disorders, reduced urine, kidney stones. Sulfadoxine can increase urine volume

Allergic reactions

Allergic reactions including skin rashes, joint stiffness and fever, swelling of the throat, face, and other parts of the body

Bones

Joint pain

Lungs

Allergic reactions in the lungs

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [MA166 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Protect from light and moisture.

Do not use this medicine after the expiry date stated on the carton or blister, after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [MA166 trade name] contains

- The active ingredients are pyrimethamine 12.5 mg and sulfadoxine 250 mg.
- The other ingredients of [MA166 trade name] are lactose monohydrate, maize starch, erythrosine soluble colour, povidone, microcrystalline cellulose, silica colloidal anhydrous, sodium bicarbonate, croscarmellose sodium, sucralose, orange flavour, purified talc and magnesium stearate.

What [MA166 trade name] looks like and contents of the pack

Pink, round-shaped, flat, bevel edge dispersible tablet, scored on one side and plain on the reverse.

[MA166 trade name] is available in white, opaque, rigid PVC/PVDC-Alu blister cards. Each blister card contains 3 tablets.

Pack sizes: 10x3, 50x3, 100x3

Supplier and Manufacturer

Universal Corporation Limited
Club Road, Plot No. 13777
P.O.Box 1748-00902
Kikuyu
Kenya

Pyrimethamine/sulfadoxine
12.5mg/250mg dispersible tablets
(Universal Corporation Ltd), MA166

WHOPAR Part 3

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Tel. No.: +254 20 2693835 / 20 2693836

Fax No.:

Email: info@ucl.co.ke

For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>