

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

[MA158 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 [MA158 trade name] is and what it is used for
2. What you need to know before you take [MA158 trade name]
3. How to take [MA158 trade name]
4. Possible side effects
5. How to store [MA158 trade name]
6. Contents of the pack and other information

1. What [MA158 trade name] is and what it is used for

[MA158 trade name] contains two medicines: pyrimethamine and sulfadoxine, used to prevent malaria in children.

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 your child.

2. What you need to know before you take [MA158 trade name]

Do not take or give [MA158 trade name]:

- if you or your child are allergic (hypersensitive) to pyrimethamine, sulfadoxine (or another sulfonamide) or to any of the other ingredients of [MA158 trade name] (see section 6 What [MA158 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 [MA158 trade name], talk to your health care provider before taking this medicine or giving it to your child.

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

Warnings and precautions

Check with your health care provider before taking [MA158 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
- 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 [MA158 trade name] or give it to your child.

If you or your child get a skin rash or itchiness with [MA158 trade name], stop taking [MA158 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

[MA158 trade name] should not be used during the first trimester of pregnancy. During the 2nd or 3rd trimesters of pregnancy, [MA158 trade name] may be used for intermittent preventive treatment in pregnancy. [MA158 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 [MA158 trade name] should be warned that undesirable effects such as dizziness may occur, in which case they should not drive or use machines.

[MA158 trade name] contains aspartame

This medicine contains 9 mg of aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take [MA158 trade name]

Your health care provider will tell you when to start treatment with [MA158 trade name].

Children

Your health care provider will tell you how many doses of [MA158 trade name] are needed, and how often they should be taken. Each dose will be at least a month apart.

The correct dosage of [MA158 trade name] depends on the weight of your child.

If your child weighs 5 kg or more, they will be given 1 tablet of [MA158 trade name].

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

Method of administration

[MA158 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 your child.

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

Instructions for use

The following procedure should be used.

- 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 your child takes more [MA158 trade name] than they should

Because this medicine is normally given under the supervision of your health care provider your child should be given the right dose. If you think your child has taken too much [MA158 trade name], tell your health care provider.

If your child is not given [MA158 trade name] at the right time

Your child should take the medicines at the right time to have the best chance of preventing malaria. Missing a dose reduces protection but 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

Ringling 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 [MA158 trade name]

Do not store above 30°C. Protect from light. Store tablets in the blisters in the provided carton. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

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 [MA158 trade name] contains

The active substances are pyrimethamine and sulfadoxine. Each dispersible tablet contains 12.5 mg pyrimethamine and 250 mg sulfadoxine.

The other ingredients are:

- pregelatinized starch, croscarmellose sodium, colloidal silicon dioxide, microcrystalline cellulose, aspartame, orange flavour and sodium stearyl fumarate.

What [MA158 trade name] looks like and contents of the pack

White to off white, round, flat faced bevelled edge, uncoated tablet debossed with 'F' and '42' on either side of break line on one side and plain on the other side.

[MA158 trade name] is available in:

- Clear PVC/PVDC-Alu blister card containing 3 tablets of pyrimethamine/sulfadoxine 12.5mg/250mg.
Pack sizes: 1, 10, 25, 50 or 100 blister cards per carton.
- Clear PVC/PVDC-Alu blister card containing 10 tablets of pyrimethamine/sulfadoxine 12.5mg/250mg.
Pack sizes: 11 blister cards per carton.

Supplier and Manufacturer

Supplier

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

This leaflet was last revised in December 2022

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