

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[MA193 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 [MA193 trade name] is and what it is used for
2. What you need to know before you take [MA193 trade name]
3. How to take [MA193 trade name]
4. Possible side effects
5. How to store [MA193 trade name]
6. Contents of the pack and other information

1. What [MA193 trade name] is and what it is used for

[MA193 trade name] contains two medicines: pyrimethamine and sulfadoxine, used to prevent malaria in children aged less than 12 months and in adults during pregnancy.

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 [MA193 trade name]

Do not take or give [MA193 trade name]:

- if the person taking the medicine is allergic (hypersensitive) to pyrimethamine, sulfadoxine (or another sulfonamide) or to any of the other ingredients of [MA193 trade name]
(see section 6 What [MA193 trade name] contains).
- to a child who is premature or during his/her first 2 months of life
- if the person taking the medicine ever suffered blood disorders with pyrimethamine or sulfadoxine.

If you are not sure you should be given [MA193 trade name], talk to your health care provider before taking this medicine.

[†] 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 [MA193 trade name]:

- if you are suffering from a recent illness. Malaria may need to be treated with a different medicine
- if you have been treated in the past 30 days with medicines containing pyrimethamine and sulfadoxine
- if you are HIV-positive and you have been taking a combination of sulfamethoxazole and trimethoprim because this increases side effects.

If any of the above applies to you, or if you are not sure, talk to your health care provider before you take [MA193 trade name].

If you get a skin rash or itchiness with [MA193 trade name], stop taking [MA193 trade name] and talk to your health care provider.

Taking other medicines

Tell your health care provider about any other medicine that you 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 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)
- other medicines (usually for infections) which contain a sulfonamide

Pregnancy and breastfeeding

[MA193 trade name] should not be used during the first trimester of pregnancy. During the 2nd or 3rd trimesters of pregnancy, [MA193 trade name] may be used for intermittent preventive treatment in pregnancy. [MA193 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 [MA193 trade name] should be warned that undesirable effects such as dizziness may occur, in which case they should not drive or use machines.

[MA193 trade name] contains lactose monohydrate. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

This medicine may contain traces of cow's milk proteins. If you are allergic to cow's milk, talk to your health care provider before taking this medicine.

3. How to take [MA193 trade name]

Your health care provider will tell you when to start treatment with [MA193 trade name].

Pregnancy

The usual dose is 3 tablets of [MA193 trade name] which corresponds to 75 mg of pyrimethamine and 1500 mg of sulfadoxine.

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 [MA193 trade name] are given at least one month apart.

Children

Your health care provider will tell you how many doses of [MA193 trade name] are needed, and how often they should be taken. Each dose will be at least a month apart.

The correct dosage of [MA193 trade name] depends on the weight of your child.

Children weighing 5 kg or more should be given half a tablet of [MA193 trade name]. For children weighing less than 5 kg, appropriate dose adjustments cannot be made and your health care provider will choose another formulation.

Method of administration

[MA193 trade name] is a tablet to be taken by mouth.

It can be given either on an empty stomach or with food. Your health care provider will prepare the dose and give it to you or your child.

Missing a dose reduces protection but you or your child can still receive the next dose.

For use in **infants**:

- The tablet should be divided into half along the break line and the half tablet crushed.
- The crushed half tablet can be added to a small amount of semi-solid food and given to the child straight away.
- Alternatively, around 10 mL of clean drinking water should be taken in a small and clean cup or glass, and the crushed half of the tablet added.
- The cup should be gently swirled until the half 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 half-tablet. 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 [MA193 trade name] than you should

Because this medicine is normally given under the supervision of your health care provider you or your child should be given the right dose. If you think you or your child have taken too much [MA193 trade name], tell your health care provider.

If you forget to take [MA193 trade name] or to give it to your child at the right time

You and 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 [MA193 trade name]

Do not store above 30°C. Avoid excursions above 30°C.

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

Do not use this medicine after the expiry date stated on the label, carton or bottle. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that it is different from the description below.

Do not throw away any medicines in wastewater. 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 [MA193 trade name] contains

- The active ingredients are Pyrimethamine 25 mg and sulfadoxine 500 mg

- The other ingredients of [MA193 trade name] are lactose monohydrate, maize starch, povidone, sodium starch glycolate, purified talc, magnesium stearate
- There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [MA193 trade name] looks like and contents of the pack

[MA193 trade name] is packed in:

Blister packs

Clear colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing 3 tablets. Available in cartons of 30 x 3 tablets.

HDPE bottle packs

Round, opaque white plastic (HDPE) bottle containing 500 or 1000 tablets. It also contains a sachet of desiccant (drying material) and a piece of rayon wool to keep the tablets in place. The bottle has a plastic (polypropylene) foil seal and a white, plastic (polypropylene) screw cap.

Supplier and Manufacturer

Supplier

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Email:regulatory@skant.com

Manufacturer

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Fax:+91 260 2430527
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For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in June 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

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