

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 (term to be revised).
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

Information for the patient

SPAQ-CO[®] Disp 153mg+25mg/500mg ¹

Amodiaquine(as hydrochloride) +Pyrimethamine/Sulfadoxine 153mg+25mg/500mg Dispersible Tablets

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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get 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 SPAQ-CO[®] Disp 153mg+25mg/500mg is and what it is used for
2. What you need to know before you take SPAQ-CO[®] Disp 153mg+25mg/500mg
3. How to take SPAQ-CO[®] Disp 153mg+25mg/500mg
4. Possible side effects
5. How to store SPAQ-CO[®] Disp 153mg+25mg/500mg
6. Contents of the pack and other information

1. What SPAQ-CO[®] Disp 153mg+25mg/500mg is and what it is used for

SPAQ-CO[®] Disp 153mg+25mg/500mg contains two types of tablets. One contains a medicine called amodiaquine and the other contains two medicines: pyrimethamine and sulfadoxine.

SPAQ-CO[®] Disp 153mg+25mg/500mg is used to prevent malaria in children aged between 12 and 59 months during the malaria season (usually during the rainy season). SPAQ-CO[®] Disp 153mg+25mg/500mg is for use by children in the Sahel sub-region of Africa.

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 SPAQ-CO[®] Disp 153mg+25mg/500mg

Your child must not be given SPAQ-CO[®] Disp 153mg+25mg/500mg if your child:

- is allergic (hypersensitive) to amodiaquine, pyrimethamine, sulfadoxine (or another sulphonamide) or to any of the other ingredients of SPAQ-CO[®] Disp 153mg+25mg/500mg (see section 6 What SPAQ-CO[®] Disp 153mg+25mg/500mg contains).
- has ever suffered blood disorders with amodiaquine, pyrimethamine or sulfadoxine.
- has ever had liver problems with amodiaquine.

¹Trade names are not prequalified by WHO. This is the national medicines regulatory agency's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

If you are not sure your child should be given SPAQ-CO[®] Disp 153mg+25mg/500mg, talk to your health care provider before giving the medicine.

Take special care with SPAQ-CO[®] Disp 153mg+25mg/500mg

Check with your health care provider before giving SPAQ-CO[®] Disp 153mg+25mg/500mg if your child:

- is suffering from a recent illness. If your child has malaria then the child may need treatment with a different medicine
- has been treated in the past 30 days with medicines containing amodiaquine or pyrimethamine and sulfadoxine
- is HIV-positive and has been taking a combination of sulfamethoxazole and trimethoprim

If any of the above apply to your child, or if you are not sure, talk to your health care provider before you give SPAQ-CO[®] Disp 153mg+25mg/500mg to your child.

If your child gets a skin rash or itchiness with SPAQ-CO[®] Disp, stop giving SPAQ-CO[®] Disp 153mg+25mg/500mg and talk to your health care provider.

Taking other medicines

Tell your health care provider if your child is taking or has recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

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

- malaria medicines containing amodiaquine, 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

SPAQ-CO[®] Disp 153mg+25mg/500mg is intended for children and therefore no advice is given on pregnancy and breastfeeding.

Driving and using machines

SPAQ-CO[®] Disp 153mg+25mg/500mg is intended for children and effects on driving and use of machines are not relevant. Your child might feel dizzy and unsteady.

3. How to take SPAQ-CO TM Disp 153mg+25mg/500mg

Your health care provider will tell you when to start treatment with SPAQ-CO[®] Disp 153mg+25mg/500mg. To give the best protection your child should have a maximum of four courses of SPAQ-CO[®] Disp 153mg+25mg/500mg during the malaria season. Each course lasts 3 days and your health care provider might give the medicines on the first day.

The doses recommended below are suitable for children aged 12 to 59 months.

	Dose (child aged 12–59 months)	
	Amodiaquine (as hydrochloride) tablet (153 mg)	Pyrimethamine/sulfadoxine tablet (25 mg/500 mg)
Day 1	1 tablet	1 tablet
Day 2	1 tablet	–
Day 3	1 tablet	–

There should be a gap of 1 month between the courses.

The tablets can be dispersed with water.

For administration of SPAQ-CO[®] Disp 153mg+25mg/500mg on the first day of treatment you need 2 clean cups or glasses:

- (1) Add approximately 10 mL of drinking water in each cup/glass;
- (2) Place one pyrimethamine/sulfadoxine dispersible tablet (only needed as the first dose for a treatment) in one cup/glass, and one amodiaquine dispersible tablet in the other cup/glass;
- (3) Let the tablets disperse, then shake thoroughly the mixtures obtained and give immediately to drink to the child the contents of the two cups/glasses;
- (4) Rinse the two cups/glasses with additional approximately 10 mL of drinking water respectively and have the child drink the contents to assure that the whole dose is taken.

For administration of SPAQ-CO[®] Disp 153mg+25mg/500mg on the second and third day of treatment you need one clean cup or glass:

- (1) Add approximately 10 mL of drinking water in the cup/glass;
- (2) Place one amodiaquine dispersible tablet in the cup/glass;
- (3) Let the tablet disperse, then shake thoroughly the mixture obtained and give immediately to drink to the child the contents of the cup/glass;
- (4) Rinse the cup/glass with additional approximately 10 mL of drinking water respectively and have the child drink the contents to assure that the whole dose is taken.

If your child vomits within 30 minutes of taking the tablet then you may need to give another tablet. Wait for 10 minutes before giving the replacement dose.

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

If your child is given more SPAQ-CO[®] Disp 153mg+25mg/500mg than the child should have

If your child has been given too much SPAQ-CO[®] Disp 153mg+25mg/500mg, tell your health care provider.

If your child does not get SPAQ-CO[®] Disp 153mg+25mg/500mg at the right time

Your child should take the medicines at the right time to have the best chance of preventing malaria. If your child misses a dose, give the missed dose as soon as you can and give the next one after at least 8 hours. If your child misses a full course (a month after the previous one) then the child will be less well protected but your child should still receive the next course.

4. Possible side effects

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

The most common side effects of amodiaquine are vomiting, stomach pain, fever, diarrhoea, itching, headaches and rash. 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 amodiaquine and pyrimethamine/sulfadoxine usually in adults treated for malaria but not when these medicines are used for seasonal malaria prevention in children. These side effects include:

Mental and nervous system disorders:

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

Digestive system

Loss of appetite, 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

Skin reactions caused by sunlight, slight hair loss, grey coloration of the skin and the lining of the nose, mouth, etc,

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 any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SPAQ-CO[®] Disp 153mg+25mg/500mg

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

Do not store above 30°C, store the tablets in blisters in the provided box/carton. Protect from light.

Do not use this medicine after the expiry date stated on the pack.

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 SPAQ-CO[®] Disp 153mg+25mg/500mg contains

- The active substances are amodiaquine and pyrimethamine/sulfadoxine.
- The other ingredients of SPAQ-CO[®] Disp 153mg+25mg/500mg is are as follows:

Amodiaquine (as hydrochloride) 153mg dispersible tablets

Povidone
Sodium bicarbonate
Microcrystalline cellulose
Crosslinking carboxymethyl cellulose sodium
Sucralose
Magnesium stearate

Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablets

Hypromellose
Low-substituted hydroxypropyl cellulose
Sucralose
Magnesium stearate

What SPAQ-CO[®] Disp 153mg+25mg/500mg looks like and contents of the pack

Amodiaquine (as hydrochloride) 153mg dispersible tablets

Yellow round tablets debossed with “AQ” on one side and a score line on the other side.

Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablets

White round tablets debossed with “SP” on one side and a score line on the other side.

On both tablets, the score lines are only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets are packaged in colourless transparent PVC/Al blister containing three Amodiaquine (as hydrochloride) 153mg dispersible tablets and one Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablet.

Pack size: 50 co-blister cards per box
60 boxes per carton.

Supplier and Manufacturer

Guilin Pharmaceutical Co., Ltd. (a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.)
No. 43 Qilidian Road
Guilin
Guangxi
China, 541004
Tel: +86 773 3841973
Fax: +86 773 3841973
E-mail: overseas@guilinpharma.com

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

Guilin Pharmaceutical(Shanghai) Co., Ltd.
Rm. 1101, Bldg. B, #1289 Yishan Rd., Shanghai 200233, P.R. China
Tel:+86 21 60133935
Fax:+86 21 60133936
E-mail: fudw@fosunpharma.com

This leaflet was drafted in January 2019

Section 6 was updated in March 2020

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal/>.