

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

[HA691 trade name][†]
Sulfamethoxazole/trimethoprim

*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 [HA691 trade name] is and what it is used for
2. What you need to know before you take [HA691 trade name]
3. How to take [HA691 trade name]
4. Possible side effects
5. How to store [HA691 trade name]
6. Contents of the pack and other information

1. What [HA691 trade name] is and what it is used for

[HA691 trade name] is used in patients with HIV to prevent or treat certain infections that they can catch. It can be used in:

- infants and children aged under 5 years
- adults and children over 5 years who have severe HIV disease
- patients who have tuberculosis
- patients who live where they can easily catch malaria or other severe infections

[HA691 trade name] can be used to stop you catching:

- a lung infection (pneumonia) caused by an organism called *Pneumocystis jirovecii* pneumonia
- a brain infection (toxoplasmosis encephalitis)
- malaria
- several other infections

The medicine can also be used for treating:

- *Pneumocystis jirovecii* pneumonia
- toxoplasmosis encephalitis

[HA691 trade name] is a combination of two antibiotics: sulfamethoxazole and trimethoprim. The two substances work together to stop the growth of certain organisms that cause infections.

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

2. What you need to know before you take [HA691 trade name]

Always take your medicine exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

These tablets are not suitable for patients who cannot swallow tablets. You may break the tablet in half if necessary but you (or your child) must not crush or chew the tablets.

Taking the tablets with food may help to stop you feeling sick (nausea). Drink plenty of fluid such as water while you are taking this medicine.

Preventing serious infections in people living with HIV

If you are living with HIV, your health care provider may recommend that you take {DotWPPproductName} regularly to **prevent serious infections** such as *Pneumocystis jiroveci* lung infections, infection due to *Toxoplasma* or malaria, particularly if you live in an area where malaria or severe infections are common.

The dose depends on how much you weigh, as follows:

Body Weight	Dose
6 to less than 14 kg	½ tablet daily
14 to less than 25 kg	1 tablet daily
25 kg and over	2 tablets daily

For patients weighing less than 6 kg, other products that can provide a lower dose of the active substances in this medicine may be used.

Treating serious infections in people living with HIV

If you are living with HIV and get certain other serious infections, your health care provider may prescribe a different dose of [HA691 trade name]. The dose of [HA691 trade name] and how long you need to take it depends on the infection you have and how bad it is.

Your health care provider will work out the dose needed, which is usually based on body weight:

- To treat a lung infection caused by *Pneumocystis jiroveci*, [HA691 trade name] is taken 3 to 4 times daily for 14 to 21 days; your health care provider will work out a suitable number of tablets for each dose. These will supply around 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim per dose.
- To treat a brain infection caused by *Toxoplasma* (toxoplasmosis encephalitis), the medicine is taken 2 times daily; your health care provider will work out a suitable number of tablets for each dose. These will supply around 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim per dose.

If you have kidney problems, your health care provider may prescribe a lower dose of {DotWPPproductName}.

If you take more [HA691 trade name] than you should

If you accidentally take too many tablets, immediately contact your health care provider or nearest emergency department. Take the tablet container with you so that you can easily describe what you have taken. If you have taken too much sulfamethoxazole/trimethoprim, you may feel or be sick, feel dizzy or confused.

If you forget to take [HA691 trade name]

It is important not to miss a dose. If you miss a dose of this medicine, contact your health care provider for advice. Do not take a double dose to make up for a forgotten tablet.

If you vomit (are sick) less than 1 hour after taking this medicine, take another dose. You do not need to take another dose if you were sick more than 1 hour after taking [HA691 trade name].

If you stop taking [HA691 trade name]:

Don't stop taking this medicine without checking with your health care provider. Stopping your tablets too early may no longer protect you from the infection or cause it to come back.

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

3. How to take [HA691 trade name]

Always take your medicine exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

These tablets are not suitable for patients who cannot swallow tablets. You may break the tablet in half if necessary but you (or your child) must not crush or chew the tablets.

Taking it with food may help to stop you feeling sick (nausea). Drink plenty of fluid such as water while you are taking this medicine.

Preventing serious infections in people living with HIV

If you are living with HIV, your health care provider may recommend that you take {DotWPPproductName} regularly to **prevent serious infections** such as *Pneumocystis jiroveci* lung infections, infection due to *Toxoplasma* or malaria, particularly if you live in an area where malaria or severe infections are common.

The dose depends on how much you weigh, as follows:

Body Weight	Dose
14 to less than 25 kg	½ tablet daily
25 kg and over	1 tablet daily

For patients weighing less than 14 kg, other products that can provide a lower dose of the active substances in this medicine may be used.

Treating serious infections in people living with HIV

If you are living with HIV and get certain other serious infections, your health care provider may prescribe a different dose of [HA691 trade name]. The dose of [HA691 trade name] and how long you need to take it depends on the infection you have and how bad it is: Your health care provider will tell you the dose needed, which is usually based on body weight.

- To treat a lung infection caused by *Pneumocystis jiroveci*, [HA691 trade name] is taken 3 to 4 times daily for 14 to 21 days; your health care provider will work out a suitable number of tablets for each dose. These will supply around 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim per dose.
- To treat a brain infection caused by *Toxoplasma* (toxoplasmosis encephalitis), the medicine is taken 2 times daily; your health care provider will work out a suitable number of tablets for each dose. These will supply around 25 mg/kg sulfamethoxazole and 5 mg/kg trimethoprim per dose.

If you have kidney problems your health care provider may prescribe a lower dose of {DotWPPproductName}

If you take more [HA691 trade name] than you should

If you accidentally take too many tablets, immediately contact your health care provider or nearest emergency department. Take the tablet container with you so that you can easily describe what you have taken. If you have taken too much sulfamethoxazole/trimethoprim, you may feel or be sick, feel dizzy or confused.

If you forget to take [HA691 trade name]

It is important not to miss a dose. If you miss a dose of this medicine, contact your health care provider for advice. Do not take a double dose to make up for a forgotten tablet.

If you vomit (are sick) less than 1 hour after taking this medicine, take another dose. You do not need to take another dose if you were sick more than 1 hour after taking [HA691 trade name].

If you stop taking [HA691 trade name]

Don't stop taking this medicine without checking with your health care provider. Stopping your tablets too early may no longer protect you from the infection or cause it to come back.

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

4. Possible side effects

Like all medicines, [HA691 trade name] can cause side effects, although not everybody gets them.

You may develop an allergic reaction to this medicine (as described in Section 2).

Chances of an allergic reaction are very rare (fewer than 1 in 10 000 people are affected). **Tell your health care provider immediately if you have an allergic reaction and do not take any more [HA691 trade name].**

In addition, if any of the following side effects gets serious, or if you notice any other unexpected or unusual symptoms not listed in this leaflet, please tell your health care provider.

Very common side effects

(may affect more than 1 in 10 people):

- high levels of potassium in your blood, which can cause abnormal heart beats (palpitations).

Common side effects

(may affect up to 1 in 10 people):

- a fungal infection called thrush or candidiasis which can affect for example your mouth or vagina.
- headache
- feeling sick (nausea)
- diarrhoea
- skin rashes

Uncommon side effects

(may affect up to 1 in 100 people)

- being sick (vomiting)

Very rare side effects

(may affect up to 1 in 10 000 people)

- sudden wheeziness or difficulty breathing
- extreme tiredness, abnormal bruising or bleeding or signs of infection, such as sore throat and high temperature. These may be signs of reduced:
 - red blood cells, which can make the skin pale and cause weakness or breathlessness (anaemia),
 - blood platelets (that help to stop bleeding) and
 - white blood cells (that help defend against infections)
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Henoch-Schonlein purpura (a rash which appears as purple spots on the skin)
- mouth ulcers, cold sores and ulcers or soreness of your tongue
- blisters on your skin or inside your mouth, nose, vagina or bottom
- inflammation of your eye which causes pain and redness
- rash or sunburn when you have been outside (even on a cloudy day)
- abnormal blood tests, including low levels of sodium in your blood
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. This can occur at the same time as unexpected bleeding or bruising.

- severe diarrhoea containing blood or mucus (antibiotic associated colitis including pseudomembranous colitis), which may develop into complications that are life-threatening.
- muscle or joint pain and muscle weakness
- excessive breakdown of muscle tissue which can result in muscle pain, dark urine and kidney problems.
- Difficulty passing urine, passing more or less urine than usual.
- kidney problems (you may notice tiredness, swelling or puffiness in the face, belly, thighs or ankles or problems with urination)
- sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- problems controlling your movement
- fits (convulsions or seizures)
- feeling unsteady or giddy
- ringing or other unusual sounds in your ears
- tingling or numbness in your hands and feet
- seeing or hearing things that are not there (hallucinations)
- depression
- loss of appetite
- inflammation of the pancreas (symptoms may include severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting)

Side effects of which it is not known how often they may occur

- abnormal heart rhythm (torsade de pointes, ventricular tachycardia) – you may notice sudden dizziness chest pain, palpitation, shortness of breath and become suddenly unconscious.
- pain in the abdomen (belly)
- skin lumps or hives (raised, red or white, itchy patches of skin)
- severe kidney problems
- weakness, feeling tired, sleeplessness
- nervousness or agitation
- lack of emotion or indifference to your surroundings (apathy)
- DRESS (drug reaction with eosinophilia and systemic symptoms) that appears initially as flu-like symptoms and a rash starting on the face and later spreading further over the body with a high temperature and swollen lymph nodes. The reaction can be life-threatening.
- purpura (purple spots or pinpoint on the skin)
- plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweet's syndrome)

In patients with HIV/AIDS, the following side effects may occur more frequently than in patients without HIV/AIDS:

- allergic reactions
- high levels of potassium in your blood, which can cause abnormal heart beats (palpitations).
- changes in blood tests, including low levels of sodium in your blood and higher blood levels of liver enzymes
- abnormal bruising or bleeding or signs of infection, such as sore throat and high temperature because of low levels of certain blood cells
- excessive breakdown of muscle tissue which can result in muscle pain, dark urine and kidney problems

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 [HA691 trade name]

Store at or below 30°C. Protect from light.

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

Do not use this medicine after the expiry date stated on the bottle, carton and blister 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 [HA691 trade name] contains

- The active ingredients are sulfamethoxazole and trimethoprim.
- The other ingredients of [HA691 trade name] are povidone, magnesium stearate, docusate sodium and sodium starch glycolate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [HA691 trade name] looks like and contents of the pack

[HA691 trade name] is a white, capsule-shaped, uncoated tablet. It is biconvex (rounded on top and bottom) and debossed (stamped into) with 'M' and 'L', separated by a break-line, on one side and plain on the other side. The break line can be used to divide [HA691 trade name] into equal doses.

[HA691 trade name] is packaged:

- in a round white opaque plastic bottle (HDPE) containing 500 or 1000 tablets and closed with a white, ribbed plastic (polypropylene) screw cap with a liner inside, or
- in a white opaque ribbed plastic bottle (HDPE) containing 500 or 1000 tablets in a plastic (polyethylene) bag with a tag seal (aluminium) and closed with a round white, plastic (HDPE) cap.
- in a clear colourless plastic (PVC) on aluminium foil blister cards, each containing 10 tablets. Available in packs of 10x10 tablets.

Supplier and Manufacturer

Supplier

Milan Laboratories (India) Pvt Ltd
303&304, Odyssey IT park
Road No. 9, Opposite MIDC Office
Wagle Estate,
Thane- Mumbai,
Maharashtra 400 604
India
{tel}+91 22 6159 7733
{fax}+91 22 2587 7736
{e-mail} info@milanlabs.com

Manufacturer

Milan Laboratories (India) Pvt Ltd
Plot No. 35/36/63/64/65/67
Jawahar Coop Industrial Estate Ltd
Kamothe, Panvel
Navi Mumbai
Maharashtra 410 209
India
{tel}+91 22 4584 7733/34/35
{fax} Not applicable
{e-mail} info@milanlabs.com

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

Country: India

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