

Shal'Artem / Shal'Artem Forte

Artemether and Lumefantrine Tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, 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 symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

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1. WHAT SHAL'ARTEM / SHAL'ARTEM FORTE TABLETS ARE AND WHAT THEY ARE USED FOR

Shal'Artem / Shal'Artem Forte Tablets contains two substances called artemether and lumefantrine. They belong to a group of medicines called anti-malarials, which interfere with the energy production in the malarial parasite ultimately results in the death of it.

Shal'Artem / Shal'Artem Forte Tablets is used for the treatment of malaria infections caused by a parasite called "Plasmodium falciparum" (when it is not cured by chloroquine and sulfadoxine-pyrimethamine combination).

2. BEFORE TAKING SHAL'ARTEM / SHAL'ARTEM FORTE TABLETS

Do not take Shal'Artem / Shal'Artem Forte Tablets if

- allergic to any of the constituents of Shal'Artem / Shal'Artem Forte Tablets.
- an abnormality in the rhythm of heartbeats (slow or fast heartbeats) or severe heart disease.
- an impairment in the electrolyte (potassium and magnesium) levels in blood.
- Suffering from a severe type of malaria infection.

Taking other medicines (drug-drug interactions)

Please tell your health care provider if you take or have recently taken: any other medicine to treat or prevent malaria, medicines for your heart, antipsychotic medicines (to treat disorders of mind), antidepressants (to alleviate mood disorder), antibiotics, antifungal medicines, medicines to treat HIV infection, birth control pill.

Shal'Artem/ Shal'Artem Forte with food and drink (drug-food interactions)

Shal'Artem/ Shal'Artem Forte should be taken with food or a milky drink.

Pregnancy and breast-feeding

Ask your health care provider for advice before taking Shal'Artem / Shal'Artem Forte Tablets when you are pregnant or breast-feeding because they are not recommended in the first 3-months of pregnancy. You should not breast-feed if you are taking or have taken this medicine at least 1 week before.

Driving and using machines

Driving and use of machinery are not recommended because Shal'Artem / Shal'Artem Forte Tablets may cause impairment in balance.

3. HOW TO TAKE SHAL'ARTEM / SHAL'ARTEM FORTE TABLETS

How much to take

You should check with your health care provider if you are not sure about how to take.

Shal'Artem / Shal'Artem Forte Tablets

A standard 3-day treatment schedule for Shal'Artem / Shal'Artem Forte Tablets depending on the weight of patient is recommended as follows.

Shal'Artem Tablet Dosage - for pack of 24 tablets:

Body Weight	Day 1		Day 2		Day 3	
	0 Hours	8 Hours	Morning	Evening	Morning	Evening
5 to 14.9kg	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
15 to 24.9kg	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets
25 to 34.9kg	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets
Adults & children 35kg & above	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets

Shal'Artem Tablet Dosage - for pack of 18 tablets:

Body Weight	Day 1		Day 2		Day 3	
	0 Hours	8 Hours	Morning	Evening	Morning	Evening
5 to 14.9kg	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
15 to 24.9kg	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets
25 to 34.9kg	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets

Shal'Artem Tablet Dosage - for pack of 12 tablets:

Body Weight	Day 1		Day 2		Day 3	
	0 Hours	8 Hours	Morning	Evening	Morning	Evening
5 to 14.9kg	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
15 to 24.9kg	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets

Shal'Artem Tablets are available in different pack sizes having 8, 12, 18 and 24 tablets. So can choose the pack of Shal'Artem / Shal'Artem Forte Tablets according to the body weight.

Shal'Artem Forte Tablets

For Adults: A standard 3-day treatment schedule, with a total of 6 doses, is recommended as follows.

Total doses	Dosage regimen					
6 Tablets	Day 1		Day 2		Day 3	
	0 Hrs.	8 Hrs.	24 Hrs.	36 Hrs.	48 Hrs.	60 Hrs.
	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet

Shal'Artem / Shal'Artem Forte Tablets should be taken with food or drinks having high quantity of fat fat such as milk.

If vomiting occurs within one hour of taking Shal'Artem / Shal'Artem Forte Tablets a repeat dose should be taken.

Shal'Artem / Shal'Artem Forte Tablets should be cautiously used if patient have severe kidney and liver problems.

If you take more amount of Shal'Artem / Shal'Artem Forte than you should

Contact your health care provider immediately and say exactly how many tablets are taken. Your health care provider will advise you what to do. It is important to contact your health care provider even if feeling well.

4. POSSIBLE SIDE EFFECTS

Shal'Artem / Shal'Artem Forte Tablets is generally well-tolerated. It may cause following side effects.

- Nausea, vomiting, diarrhea, stomach pain and loss of appetite are common.
- Other side effects are headache, giddiness (loss of balance), pain in joints and muscles, tiredness, itching, rashes and disturbance in sleep and gait.
- Allergic reactions are rare,
- In children less than 5 years old it may cause personality disorders.

5. HOW TO STORE SHAL'ARTEM / SHAL'ARTEM FORTE TABLETS

Do not store above 30°C. Protect from the sunlight. Keep out of the reach of children.

Do not use Shal'Artem / Shal'Artem Forte Tablets after the expiry date which is stated on the pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. FURTHER INFORMATION

What Shal'Artem / Shal'Artem Forte Tablets contains

The active substances in **Shal'Artem Tablets** are: Artemether 20mg, Lumefantrine 120mg.

The other ingredients are: Microcrystalline cellulose, maize starch, colloidal anhydrous silica, purified talc, magnesium stearate, sodium starch glycolate and hydroxypropyl cellulose.

The active substances in **Shal'Artem Forte Tablets** are: Artemether 80mg, Lumefantrine 480mg.

The other ingredients are: Microcrystalline cellulose, maize starch, colloidal anhydrous silica, purified talc, magnesium stearate, triacetin, ethylcellulose, hypromellose, sodium starch glycolate and hydroxyl propyl cellulose, Colour : Yellow Iron Oxide USP, Lake Quinoline Yellow, Titanium Dioxide.

What are the pack size of Shal'Artem Tablets?

Shal'Artem Tablets: Available as a pack of strip with 8 tablets in each strip and packs of 1 strip with 12, 18 and 24 tablets in it.

Shal'Artem Tablet: Available as a pack of 3 x 8 tablets.

Zambia Lic. No.: 075/094 Method of sale in Zambia: POM

NAFDAC Reg. No.: A4-8658 PPB Reg. No.: H2014/CTD648/242

Shal'Artem Tablet: Available as a pack of 24's tablets.

PPB Reg. No.: H2014/CTD648/242

Shal'Artem Tablet: Available as a pack of 24's, 18's & 12's tablets.

NAFDAC Reg. No. A4-8658

Shal'Artem Forte Tablets: A pack of 1 strip with 6 tablets in it.

Zambia Lic. No.: 075/093 Method of sale in Zambia: POM

NAFDAC Reg. No.: A4-8201 PPB Reg. No.: H2014/CTD646/637

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