

Name of the medicinal product
MALOXINE tablets
Sulfadoxine 500 mg/pyrimethamine 25 mg

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this package leaflet:

1. WHAT MALOXINE IS AND WHAT IT IS USED FOR
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1. WHAT MALOXINE IS AND WHAT IT IS USED FOR?

This medicine is an anti-malarial. Malaria is a disease occurring when small parasites are passed from one person to another by the bites of some mosquitoes present in tropical countries.

Maloxine is used for:

- the intermittent prevention of malaria in pregnant women.
- the treatment of uncomplicated malaria in combination with artesunate.

2. BEFORE YOU TAKE MALOXINE?

Do not take MALOXINE in the following cases:

- history of allergy to one of the components,
- serious liver or kidney disease,
- history of hepatitis due to administration of sulfadoxine or pyrimethamine.

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

Be careful with MALOXINE: If you have skin rash, angina, mouth ulceration, CONSULT YOUR DOCTOR IMMEDIATELY.

IF YOU HAVE ANY DOUBT DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking other medicines

If you are taking or have recently taken another medicine, even without prescription, inform your doctor or pharmacist.

Pregnancy and Breastfeeding:

The use of this medicine is not recommended during breastfeeding.

IN GENERAL, ALWAYS ASK YOUR DOCTOR OR PHARMACIST BEFORE TAKING A MEDICINE DURING PREGNANCY OR WHILE BREASTFEEDING.

Driving vehicles and use of machines

Not relevant.

3. HOW TO TAKE MALOXINE

Dosage

The usual dosage is as follows:

Intermittent prevention of malaria in pregnant women:

3 tablets as a single dose to be taken twice during pregnancy. The first intake during the 2nd trimester and the second intake during the 3rd trimester of pregnancy. In some cases your doctor can prescribe a third dose. The last dose must be taken not later than 30 days before the expected date of delivery.

3 days treatment of uncomplicated malaria in combination with artesunate 4mg/kg once daily:

Day 1:

- Adults: pyrimethamine 75 mg and sulfadoxine 1.5 g, equivalent to 3 tablets + artesunate daily dose
- Children: the usual dose is ½ tablet per 10 kg of weight + artesunate daily dose
- Children of 30 - 50 kg (10 to 15 years): 1.5 to 2 tablets + artesunate daily dose
- Children of 20 - 30 kg (6 to 10 years): 1 to 1.5 tablet + artesunate daily dose
- Children of 12 - 20 kg (30 months to 6 years) 1 crushed tablet + artesunate daily dose
- For children with body weight less than 12 kg (under 30 months): ½ crushed tablet + artesunate daily dose

Days 2 and 3: artesunate 4mg/kg once daily

THIS MEDICINE HAS BEEN GIVEN UNDER SPECIFIC CIRCUMSTANCES:

- IT MAY NOT BE ADAPTED FOR ANY OTHER CASE
- DO NOT PASS IT ON TO OTHERS

Method and route of administration

Oral route

Take the tablets with a glass of water.

If you have taken more MALOXINE tablets than you should:

The overdose is hazardous. The prescribed dosage should not be exceeded. In the event of anorexia, vomiting, seizures, INFORM YOUR DOCTOR IMMEDIATELY.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, MALOXINE tablets may cause side effects, although not everybody gets them:

- Rare gastro-intestinal disorders
- Signs of skin allergic reactions : rash, itching
- Blood disorders: abnormal decreased levels of red blood cells, white blood cells, platelets
- Renal disorders
- Hepatic function disorders

Skin reactions or blood disorders require an immediate and definitive discontinuation of the treatment. If you notice any side effects not mentioned in this package leaflet, or if some side effects become serious, please tell your doctor or pharmacist.

5. HOW TO STORE MALOXINE

Keep out of the reach and sight of children.

Do not use MALOXINE after the expiry date stated on the outer pack.

Store at a temperature not exceeding 30°C

Medicines must not be disposed of down the drain or with the domestic waste. Ask your pharmacist what you should do with unused medicines. These measures are to protect the environment.

6. FURTHER INFORMATION

What does MALOXINE contain?

The active substances are sulfadoxine (500 mg) and pyrimethamine (25 mg)

The other ingredients are: maize starch, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), purified talc, magnesium stearate, crosscarmellose sodium

What MALOXINE looks like and contents of the pack?

This medicine is presented in the form of white, round, scored tablets engraved Maloxine. Pouches of 3 tablets in blister pack.

MALOXINE® is a registered trademark

of Exphar s.a. Zoning de Nivelles, zone II, Avenue Thomas Edison, 1402 Thines, Belgium

Manufacturer

Gracure Pharmaceuticals Ltd.,
E-105 Industrial area, Phase III, Bhiwadi (Raj) INDIA.

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