

VARDMOX - 500

AMOXICILLIN

Amoxicillin capsules 500 mg

PATIENTS INFORMATION

PLEASE READ THIS LEAFLET BEFORE TAKING YOUR MEDICINE.

Always follow your doctor's advice. If there is anything you do not understand, or if you have any questions, please ask your doctor or pharmacist (chemist).

What is VARDMOX - 500?

TRADE NAME: Vardmox-500

INTERNATIONAL NONPROPRIETARY NAME: Amoxicillin

DOSAGE FORM: capsules

ATC code: J01CA04

COMPOSITION:

Amoxicillin trihydrate 500 mg

EXCIPIENTS:

Purified talc..... BP

Magnesium Stearate..... BP

PHARMACEUTICAL GROUP: antibiotic group of penicillin

MECHANISM OF ACTION: Amoxicillin binds to penicillin-binding protein 1A (PBP-1A) located inside the bacterial cell wall. Penicillins acylate the penicillin-sensitive transpeptidase C-terminal domain by opening the lactam ring. This inactivation of the enzyme prevents the formation of a cross-link of two linear peptidoglycan strands, inhibiting the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that amoxicillin interferes with an autolysin inhibitor.

Why has your doctor prescribed VARDMOX - 500?

VARDMOX - 500 can treat a wide range of infections including those of the chest (bronchitis or pneumonia), tonsils (tonsillitis), ears (otitis media), sinuses (sinusitis), the bladder or the urethra (the tube which carries urine from the bladder), kidneys, the female reproductive system including infections caused by difficulties during childbirth (puerperal sepsis and septic abortion), abdomen (intra-abdominal sepsis and peritonitis), heart (endocarditis), blood (septicaemia), skin, teeth and gums (abscesses). VARDMOX - 500 can also be used to treat gonorrhoea (a sexually transmitted infection), and typhoid and paratyphoid (fevers caused by a group of bacteria called Salmonella).

VARDMOX - 500 may also be used in combination with other medicines to treat duodenal and gastric ulcer disease.

PREGNANCY AND LACTATION

Pregnancy Teratogenic Effects. Pregnancy Category B. this drug should be used during pregnancy & lactation only if clearly needed.

Before taking your medicine Let your doctor know if any of the following apply to you:

- You have ever had a skin rash or swelling of the face or neck when taking any antibiotic
- You know that you are allergic to penicillin (or any other antibiotic)
- You are taking a contraceptive pill (in which case you will need to take extra contraceptive precautions such as using a condom)
- You have, or you think you have, glandular fever
- You are breast-feeding
- You have been treated for kidney problems
- You are taking any medicine (such as warfarin) to prevent blood clots
- You are taking allopurinol for conditions such as gout which can be caused by uric acid build-up.
- Should not be used in children under 12 years old.

If any of the above applies to you, your doctor may decide that you need a different dose of VARDMOX - 500 or a different medicine instead of VARDMOX - 500.

How to take VARDMOX – 500?

Your doctor will tell you how many capsules you should take. Your doctor's instructions are on the label of the capsules' container, so read it carefully. If you have any questions talk to your doctor or pharmacist. VARDMOX - 500 Capsules should be swallowed with water. You should drink several more glasses of water each day of your treatment, unless told otherwise by your doctor. For most infections you have to take three 250 mg capsules a day. This can be increased to 500 mg three times a day if the infection is severe. For severe or frequent chest infections your doctor may recommend taking 3 g two times a day. Infections of the bladder or urethra (water infections) can be treated with two 3 g doses taken within 10-12 hours of each other. Teeth and gum infections (abscesses) can be treated with two 3 g doses taken within eight hours between each other. Gonorrhoea (a sexually transmitted infection) can be treated with a single 3 g dose. When treating ulcer disease, 750 mg or 1 g of VARDMOX - 500 is given twice a day for seven days. People who have had heart problems may need an antibiotic when they go to the dentist or if they have to go into hospital for surgery to prevent them from getting a heart infection (endocarditis). People who are having dental treatment without a general anaesthetic may need 3 g VARDMOX - 500 before the dental treatment. A second 3 g dose may be needed six hours later. People who are having dental treatment with a general anaesthetic may need a 3 g dose four hours before anaesthesia followed by another 3 g dose straight after the dental treatment has finished. People who are having surgery in hospital will usually be given VARDMOX - 500 by injection before their treatment and will be given a 500 mg dose six hours later by mouth or by injection.

ulcer disease, 750 mg or 1 g of VARDMOX - 500 is given twice a day for seven days. People who have had heart problems may need an antibiotic when they go to the dentist or if they have to go into hospital for surgery to prevent them from getting a heart infection (endocarditis). People who are having dental treatment without a general anaesthetic may need 3 g VARDMOX - 500 before the dental treatment. A second 3 g dose may be needed six hours later. People who are having dental treatment with a general anaesthetic may need a 3 g dose four hours before anaesthesia followed by another 3 g dose straight after the dental treatment has finished. People who are having surgery in hospital will usually be given VARDMOX - 500 by injection before their treatment and will be given a 500 mg dose six hours later by mouth or by injection.

The maximum dose needed for most infections is 6 g daily given in divided doses.

When should I take VARDMOX – 500 Capsules?

Try to take your capsules so that it becomes part of your daily routine, for example when you have a meal. But remember, whenever you take your capsules, space the doses as evenly as possible throughout the day. You may take VARDMOX – 500 before, with or after food, unless the label advises a specific time. It is not normally necessary to arrange to take a dose in the middle of the night - unless your doctor has told you to do so. Try not to take more than one dose every four hours and never take two doses within one hour or so.

Keep on taking the capsules even if you feel better. You need every capsule to help you fight off the infection. If you stop taking your capsules before the end of the course, some bacteria may survive and cause the infection to come back. If you still feel unwell after finishing the treatment, go and see your doctor. Never take more than the recommended dose each day.

What if I forget to take a dose?

If you forget to take a capsule, take it as soon as you remember. Then carry on as before. Try to wait about four hours before taking the next dose. Do not take two doses within an hour or so.

What if I take too much?

If you have taken too many capsules all at once, contact your doctor or local hospital casualty department at once. Show the doctor your pack of capsules.

Information on possible side effects?

As with all medicines, some people may experience side effects with VARDMOX - 500. The more common side effects of VARDMOX – 500 that have been reported in more than 1 in 100 people taking it include:

- Nausea (feeling of sickness) or diarrhoea
- Skin rash.

Uncommon side effects that have been reported in between 1 in 100 and 1 in 1,000 people taking VARDMOX – 500 include:

- Vomiting
- Allergic skin reactions with itching e.g. 'hives' or 'nettle' rash. If you start to itch or get a rash, stop taking VARDMOX – 500 and tell your doctor at once. Rare side effects that have been reported in between 1 in 1,000 and 1 in 10,000 people. There are no rare side effects documented for VARDMOX - 500. Very rare side effects that have been reported in less than 1 in 10,000 people taking VARDMOX – 500 include:
 - Hypersensitivity or severe allergic reaction including swollen face or breathing problems.
 Tell your doctor straight away if you notice any of these symptoms and STOP taking VARDMOX - 500
 - Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist
 - Tooth discolouration. The colour usually returns to normal with brushing
 - Inflammation of the kidney. Tell your doctor that you are taking VARDMOX – 500 if you are having urine tests because VARDMOX – 500 may affect the results
 - Excessive body movements (hyperkinesia), dizziness or convulsions. People who are on high doses of VARDMOX – 500 or whose kidneys do not work properly may experience convulsions
 - Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot. Tell your doctor that you are taking VARDMOX – 500 if you are having blood tests
 - Crystalluria, forming of crystals in the urine. See your doctor straight away if you experience any of the following very rare side effects:
 - Severe diarrhoea with bleeding.
 - Notice your urine becoming darker or your faeces (otherwise known as poo) becoming paler
 - Notice your skin or the white of your eyes turning yellow
 - Convulsions
 - Difficulty or discomfort in passing urine or have cloudy urine.

If you get any other problems while taking this medicine tell your doctor or pharmacist.

SPECIAL WARNINGS:

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including Amoxycillin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Storing VARDMOX - 500

Don't take the capsules if the expiry date printed on the pack has passed.

Keep the capsules in their packet.

Store in a dry place below 25 °C.

Keep all medicines out of the reach of children - it's best to lock them in a cupboard or medicine cabinet.

If your doctor tells you to stop taking this medicine, or if for any other reason you have some capsules left over, please return them to the pharmacist. Remember, this medicine is just for you. Do not give it to anyone else. It may not be suitable for them, even if their symptoms seem to be the same as yours

Presentation: 10 X 10 capsules dosage

Legal status for supply: on prescription

Put this leaflet somewhere safe until you have finished taking all the medicine.

Manufactured by:

Vardhman Exports

A-188, T.T.C., MIDC, Khairne,

Navi Mumbai - 400 710. INDIA.

 :vmanexpo@vsnl.com