

PACKAGE LEAFLET: INFORMATION FOR THE USER

DOXY PLUS STADA

100 mg + 75 mg prolonged- release capsule

DOXYCYCLINE, AMBROXOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 any further questions, ask your doctor or pharmacist • 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 are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What DOXY PLUS STADA is and what it is used for
2. Before you take DOXY PLUS STADA
3. How to take use DOXY PLUS STADA
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1. WHAT DOXY PLUS STADA IS AND WHAT IT IS USED FOR

DOXY PLUS STADA is used in the treatment of acute and chronic respiratory diseases that are caused by microorganisms sensitive to doxycycline and followed by viscous mucus (acute worsening of chronic bronchitis and / or sinusitis).

2. BEFORE YOU TAKE DOXY PLUS STADA

Do not take DOXY PLUS STADA

- If you are allergic to Doxycycline, ambroxol, or any of the other ingredients of this medicine
- If you are under 12 years of age
- If you have impaired function of the kidneys or liver
- If you are pregnant or breast-feeding

Take special care with DOXY PLUS STADA, so you must tell the doctor

If the capsules containing doxycycline hyclate are taken in an inappropriate way (e.g., lying down), esophageal ulcers may occur, since the capsules stick to esophageal mucosa whereby, upon hydrolysis, they can release very acid solutions.

In case of damaged broncho-motor tone and relatively large amounts of mucus (in patients using antitussive agents, or in patients suffering from rare malignant cilia syndrome), DOXY PLUS STADA capsules should be taken with caution, because of the possible accumulation of mucus.

During the concomitant use of the drug DOXY PLUS STADA and medicines that lower blood sugar and prevent blood clotting, blood sugar levels and parameters of coagulation in the blood should be monitored.

Exposure to UV radiation (the sun, in the solarium or at specific workplaces), can cause phototoxic reactions on the irradiated areas of the skin that are reflected as redness, swelling, blisters and changes in skin color. Exposure to UV rays should therefore be avoided during the treatment with DOXY PLUS STADA capsules.

Frequent and severe diarrhea during or after use of DOXY PLUS STADA may be a sign of pseudomembranous enterocolitis, which is potentially life-threatening. If pseudomembranous enterocolitis occurs you should immediately stop using DOXY PLUS STADA and seek immediate medical attention.

Before using anesthetics tell your doctor that you are taking DOXY PLUS STADA.

In case of severe acute hypersensitivity reactions (eg, anaphylaxis) the treatment with capsules must be ended immediately. Specialists should undertake urgent measures on the basis of symptoms and valid therapeutic recommendations.

It is not recommended to use a capsule DOXY PLUS STADA immediately before, during or after the use of isotretinoin in the treatment of acne, because both of these medicines can in rare cases lead to a reversible increase in intracranial pressure (pseudotumor cerebri), which disappears after discontinuation of therapy.

Simultaneous use of theophylline and capsule DOXY PLUS STADA increases the odds of occurrence of side effects in the gastrointestinal tract.

As a rule, patients with acute bronchitis without chronic obstructive pulmonary disease should not be treated with antibiotics as it is in most cases a virus infection.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Capsules DOXY PLUS STADA contain doxycycline; its absorption in the gastrointestinal tract can be impeded by bivalent or trivalent cations, such as aluminum, calcium or magnesium, preparations based on iron, active coal and cholestyramine. Such ingredients and medicines should therefore be taken at a time interval of at least 2 hours.

Antibiotic rifampicin, some active substances from the group of barbiturates and other anticonvulsants (such as carbamazepine, diphenylhydantoin and primidone) and chronic alcohol intake can accelerate decomposition of doxycycline due to enzyme induction in the liver, which makes it unable to reach a therapeutically effective concentration of doxycycline by standard dosage of DOXY PLUS STADA.

DOXY PLUS STADA may potentiate the effect of sulfonyleureas and anticoagulants type dicoumarol. During combined administration blood glucose and coagulation parameters should be monitored, with reducing the dose of these medicines if necessary.

Simultaneous use of capsule DOXY PLUS STADA and cyclosporine A can lead to a reduction in defense capabilities of the organism.

Simultaneous use of capsule DOXY PLUS STADA and β -lactam antibiotics should be avoided since it can reduce antibiotic effect.

In rare cases, the safety of the contraceptive effects of hormonal contraceptives may be impaired due to the intake of capsules DOXY PLUS STADA. The use of additional, non-hormonal (eg, condoms) contraceptive methods is therefore recommended.

Taking DOXY PLUS STADA with food and drink

Do not consume milk, milk products and fruit juices containing calcium simultaneously with DOXY PLUS STADA. There should be an interval of at least 2 hours.

The use of alcohol accelerates the decomposition of doxycycline. It is necessary to avoid concomitant use of DOXY PLUS STADA prolonged- release capsules and alcohol!

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You should not take the drug DOXY PLUS STADA if you are pregnant or breast-feeding.

Driving and using machines

The individual cases of transient myopia during the use of DOXY PLUS STADA were reported. This side effect can impair your ability to drive or operate machinery.

What you need to know about excipients of DOXY PLUS STADA

DOXY PLUS STADA contains sugar. If your doctor told you have an intolerance to some sugars, contact him before taking this medicine.

3.HOW TO TAKE DOXY PLUS STADA

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Recommended dosage

On the first day you should take two DOXY PLUS STADA capsules, and every following day you should take one DOXY PLUS STADA capsule.

DOXY PLUS STADA should not be given to children under the age of 12.

Method of administration

Capsules DOXY PLUS STADA should be taken regularly, before breakfast or other meal. To avoid esophageal ulcer capsules DOXY PLUS STADA should be taken without chewing, with a lot of liquid (eg. A glass of water), in an upright position and not just before going to sleep.

Duration of treatment

Duration of treatment depends on the clinical condition of the patient. Your doctor will determine the duration of treatment.

If you take more DOXY PLUS STADA than you should

There have been no cases of poisoning with DOXY PLUS STADA. An overdose carries a risk of kidney and liver damage, and pancreatic inflammation. It may cause short-term anxiety and diarrhea. In more serious cases it may result in increased secretion of saliva, vomiting and lowering of blood pressure.

If you forget to take DOXY PLUS STADA

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

If you stop taking DOXY PLUS STADA

You will not feel any changes if you stop taking the medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DOXY PLUS STADA can cause side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Infections and infestation

Uncommon: Pharyngitis.

Very rare: pseudomembranous enterocolitis.

It should be noted that long-term or repeated use of DOXY PLUS STADA® can lead to superinfection and colonization of resistant bacteria or fungi.

Disorders of blood and lymphatic system

Not so often: Impaired coagulation.

Rare: leucopenia, leukocytosis, thrombocytopenia, anemia, lymphocytopenia, lymphadenopathy, atypical lymphocytes and granulocytes toxic granulation. These effects are reversible after discontinuation of therapy.

Immune system disorders

Uncommon: Allergic reactions, including generalized exanthema (itching), erythema (redness of the skin), urticaria (hives), pruritis, edema (local swelling) of the skin, mucous membranes or joints, asthma, skin rash on the genitals and other body parts, ill reactions resembling serum, followed by fever, headache and arthralgia.

Very rare: Severe acute hypersensitivity reactions (eg, anaphylaxis) which manifest as swelling of the face, tongue, throat, narrowing of the airway, tachycardia, shortness of breath, drop in blood pressure, circulatory collapse and cardiac arrest. It is necessary to seek urgent medical attention.

Psychiatric disorders

Very rare: Agitation and tension.

Nervous system disorders

Rare: Increased intracranial pressure (pseudotumor cerebri), which resolves after discontinuation of therapy. It manifests itself as headache, nausea, and vomiting, disturbed vision due to papillary edema.

Rare: Loss of sense of taste and smell only in certain cases and only partially.

Very rare: Convulsions or paresthesia.

Eye disorders

Mostly transient nearsightedness (myopia) is observed in individual cases in patients taking tetracyclines.

Cardiovascular disorders

Very rare: Increased heart rate, abnormal heart rhythms.

Respiratory, thoracic and mediastinal disorders

Uncommon: Hoarseness.

Very rare: Dyspnea (shortness of breath).

Gastrointestinal disorders

Common: nausea, vomiting, heartburn, gastric pressure, gases, fatty stools and diarrhea.

Uncommon: Inflammation in the mouth, difficulties swallowing and isolated cases of lingua villosa nigra.

Rare: Ulcer of esophagus.

In case of overdose there is a risk of the formation of pancreatic inflammation.

Hepatobiliary disorders

In case of overdose there is a risk of the formation of liver damage.

During pregnancy there is an increased risk for the development of liver damage.

Skin and subcutaneous tissue disorders

Very rare: redness, itching, Stevens-Johnson syndrome, exfoliative dermatitis, Lyell's syndrome.

Phototoxic reactions can occur after exposure to UV rays, sometimes with the impact to nails.

Disorders of muscle, bone and connective tissue

Very rare: Pain in muscles and joints.

Renal and urinary tract disorders

Not so often: The appearance of blood in the urine (hematuria).

Tetracycline can cause kidney damage and worsen pre-existing impaired renal function.

Serious side effects and measures for their treatment

If you experience any of the following side effects stop using DOXY PLUS STADA and immediately contact your doctor. These side effects can be life-threatening in certain circumstances.

Pseudomembranous enterocolitis

If during treatment you experience serious diarrhea that lasts a few weeks, it should be considered whether it is pseudomembranous enterocolitis. This state of the intestines, which occurs after use of antibiotics, can be life threatening and requires immediate treatment.

In this case, your doctor should discontinue the use of DOXY PLUS STADA and immediately begin the treatment. You should not be given medicines that prevent bowel movements.

Severe acute hypersensitivity reactions (eg, anaphylaxis)

In this case you should immediately stop using DOXY PLUS STADA and receive emergency medical help.

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.

5. HOW TO STORE DOXY PLUS STADA

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use DOXY PLUS STADA after the expiry date which is stated on the label, 5 years from the date of manufacture.

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 DOXY PLUS STADA contains

A hard prolonged- release capsule contains 100 mg of doxycycline in the form of doxycycline hyclate, and 75 mg of ambroxol as ambroxol chloride.

Other ingredients: gelatin, corn starch, povidone K30, shellac, sucrose, talc, erythrosine (E127), indigo carmine (E132), titanium dioxide (E171), iron (III) oxide (E172).

What DOXY PLUS STADA looks like and contents of the pack

PVC / aluminum blister.

Original package contains 10 capsules.

Pharmacotherapeutic group: Doxycycline (antibiotic from the group of tetracycline) with ambroxol

Anatomical-therapeutic-chemical classification (ATC): J01AA20

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

STADA Arzneimittel AG

Stadastrasse 2-18, Bad Vilbel, Germany

Manufacturer of the medicinal product

STADA Arzneimittel AG

Stadastrasse 2-18, Bad Vilbel, Germany