

**Package leaflet: Information for the user**  
**PERIOSTAT® 20 mg film coated tablets**  
Doxycycline

**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 dentist, 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 of the side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Periostat is and what it is used for
2. What you need to know before you take Periostat
3. How to take Periostat
4. Possible side effects
5. How to store Periostat
6. Contents of the pack and other information

**1. What Periostat is and what it is used for**

Periostat belongs to a group of medicines called tetracyclines. Tetracyclines are a type of antibiotic although the very small dose of doxycycline contained in Periostat is not high enough for Periostat to act as an antibiotic.

Periostat tablets are used in the treatment of periodontitis (a condition of the gums which can cause teeth to become loose or fall out).

The standard treatment for periodontitis is a scaling and root planing carried out by your dentist or dental hygienist. Periostat is then prescribed by your dentist as an additional treatment. The oral hygiene routine explained by your dentist or dental hygienist should continue at the same time.

The periodontium, which is made up of collagen fibres, is the part of the gum that gives support to each tooth and it is this part that is affected by periodontitis. Periodontitis is caused by the presence of bacteria at the gum line which can cause inflammation and infection of the gum.

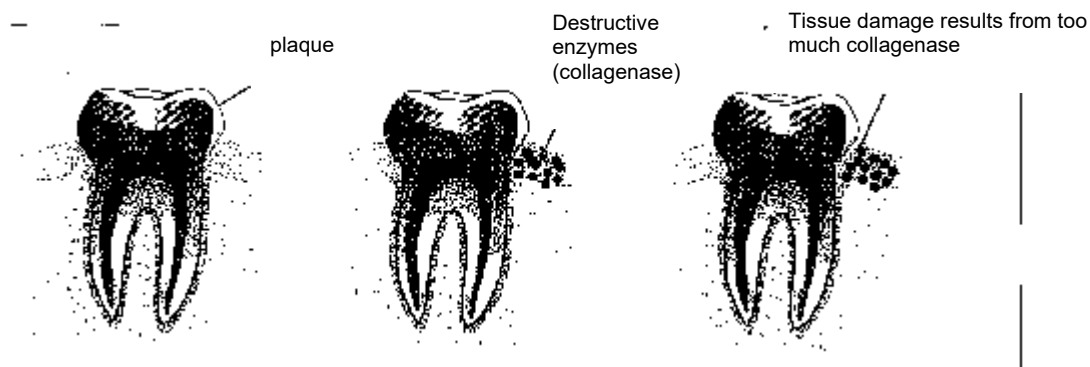
The body's immune system makes special cells to fight the gum infection. The body releases enzymes into the gums which break down the collagen fibres around the tooth and allows these special cells to get to the site of infection. Unfortunately, although the enzymes are part of the body's own defence system, they actually damage the gum. This can cause teeth to become loose or even fall out. Diagram 1 explains the causes of periodontitis.

### Diagram 1: The causes of periodontitis

Plaque and bacteria accumulate on the tooth near the gum

The body releases enzymes into the gum

The enzymes destroy the tissues supporting the tooth



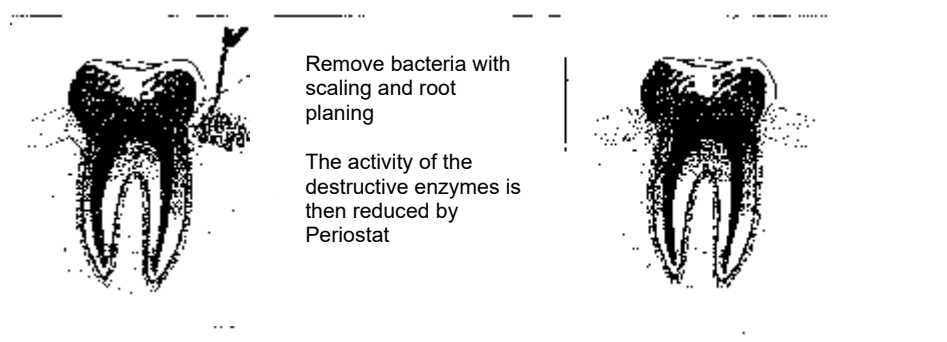
Periostat reduces the effect of the collagenase enzymes. This can make your gums healthier and increase the stability of your affected teeth.

Diagram 2 explains how scaling and root planing with the addition of Periostat treats periodontitis.

### Diagram 2: How scaling and root planing with Periostat treats periodontitis

Scaling & root planing with Periostat

The body works to restore the damaged tissue making teeth more stable



## 2. What you need to know before you take Periostat

### Do not take Periostat:

- if you are allergic to doxycycline (or any other tetracycline antibiotic e.g. oxytetracycline, tetracycline, chlortetracycline, demeclocycline or minocycline) or any of the ingredients of this medicine (listed in section 6).
- if you are pregnant or think you might be pregnant
- if you are planning to become pregnant
- if you are breast-feeding
- if you have achlorhydria (lack of acid in the stomach)

If any of the above applies to you, or if you are not sure, speak to your dentist, doctor or pharmacist before you take Periostat.

### Warnings and precautions

Talk to your dentist, doctor or pharmacist before taking Periostat if:

- you have porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour)
- you have severe diarrhoea (see Section 4 Possible side effects)
- you have myasthenia gravis (a rare muscle weakness disorder)
- you suffer from phototoxicity (skin rashes caused by sunlight). Stop taking Periostat if this happens and consult your doctor.
- you have liver problems or are taking medication which may damage your liver (see Section 4 Possible side effects)
- you have thrush (a yeast infection caused by Candida)
- you have systemic lupus erythematosus (SLE). An allergic condition which causes joint pain, skin rashes and fever (see Section 4 Possible side effects)

### Children and adolescents

Do not give this medicine to children up to 12 years of age.

### Other medicines and Periostat

Tell your dentist, doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- aluminium containing products (used to neutralise acid in your stomach)
- zinc containing products (used to treat low zinc levels)
- calcium containing products (used to treat low calcium levels or as an antacid)
- anti-coagulant medication for example warfarin (used to thin the blood)
- penicillin or rifampicin (antibiotics to treat infections)
- antacids (used to neutralise acid in your stomach)
- iron containing products (used to treat low iron levels)
- bismuth containing products (used to treat stomach ulcers)
- sucralfate-containing products (used to treat stomach ulcers)
- activated charcoal (used to treat poisoning)
- cholestyramine (used to reduce cholesterol levels and prevent heart disease, to treat itching due to liver problems and diarrhoea)
- didanosine tablets (used to treat HIV)
- quinapril (used to treat high blood pressure or heart failure)
- barbiturates, carbamazepine, phenytoin and primidone (medication to control epilepsy)
- ciclosporins (used to suppress your immune system after an organ transplant)
- methoxyflurane (a type of anaesthetic)
- isotretinoin (used to treat acne)
- sulfonylurea agents (used to treat diabetes, e.g. chlorpropamide, glibenclamide, gliclazide, glimepiride, glipizide or gliquidone)
- oral contraceptives (used to prevent pregnancy).

**Periostat with food, drink and alcohol**

Periostat should be taken at least one hour before meals.

Food containing large amounts of calcium (e.g. milk, dairy products and calcium-containing fruit juices) should be avoided until at least 2 to 3 hours after taking Periostat.

Consult with your doctor before taking Periostat if you regularly drink large amounts of alcohol.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist, doctor or pharmacist for advice before taking this medicine.

Periostat should not be used during pregnancy or if you are breast-feeding. Taking Periostat during pregnancy may result in permanent discolouration of your child's teeth.

Periostat passes into the milk of breast-feeding mothers and therefore you should not breast-feed whilst taking this medicine.

There are no clinical data regarding the potential effect of Periostat on fertility.

**Driving and using machines**

Taking Periostat may make you feel sick or dizzy. If you are affected, you should not drive or use machines until the effect has worn off.

**Periostat contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to take Periostat**

Always take this medicine exactly as your dentist, doctor or pharmacist has told you to. Check with your dentist, doctor or pharmacist if you are not sure.

The recommended dose is one tablet in the morning and one in the evening.

Periostat should be taken at least one hour before going to bed for the night and at least one hour before meals. Try and take the medication at the same times each day.

The tablets should be swallowed with a drink of water in the sitting or standing position followed by plenty of fluid. Do not lie down immediately after taking the tablet.

Periostat is usually taken for a minimum of 3 months and can be taken for up to 9 months at a time. It is important that you continue to take Periostat until your dentist tells you to stop.

**If you take more Periostat than you should**

If you accidentally take too many tablets, or someone else takes any of your medicine, you should tell your doctor at once or contact the nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

**If you forget to take Periostat**

Do not worry. If you forget to take a dose, just take the next dose as normal.

Do not take a double dose to make up for a forgotten tablet. Then go on as before.

### **If you stop taking Periostat**

Complete the prescribed course unless otherwise directed by your dentist or doctor.

If you have any further questions on the use of this medicine, ask your dentist, doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **If any of the side effects listed below occur, contact your doctor as soon as possible:**

- you have a severe allergic reaction which includes sudden wheeziness, chest pain, difficulty in breathing, sudden swelling, fever, skin rash or itching (see Section 2 What you need to know before you take Periostat)
- you have diarrhoea which is watery or contains blood due to colitis (inflammation of the intestines which can cause stomach pain, diarrhoea and other symptoms) and pseudomembranous colitis (infection of the intestines which can cause stomach pain, fever and diarrhoea) (see Section 2 What you need to know before you take Periostat)
- you have the Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting doxycycline treatment for infections with spirochete such as Lyme disease.

Other side effects are:

Very common side effects (may affect more than 1 in 10 people):

- headache
- common cold
- flu like symptoms (such as fever).

Common side effects (may affect up to 1 in 10 people):

- indigestion (heartburn)
- feeling sick
- diarrhoea
- rash
- sinusitis (inflammation of the nasal passages), coughing and bronchitis
- tooth abscess
- sore throat and sinus headache
- toothache, pain of any sort, joint and back pain
- period pains
- infection (e.g. thrush).

Uncommon side effects (may affect up to 1 in 100 people):

- muscle and gum pain

Rare side effects (may affect up to 1 in 1,000 people):

- vaginal and anal thrush (causing soreness and/or itching of the rectal and/or genital area)
- anxiety

Very rare side effects (may affect up to 1 in 10,000 people):

- dizziness
- stomach pain, constipation, dry mouth and tooth discolouration

- skin becoming sensitive to sunlight
- weakness
- hives and itching

Side effects with frequency which cannot be estimated from the available data:

- separation or loosening of a fingernail or toenail from its nail bed following exposure to sunlight or ultraviolet rays

Other side effects that have occurred in people taking other tetracyclines similar to Periostat are:

- Blood disorders. These are due to an imbalance in numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising, nose bleeds or susceptibility to infection. Porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour) has been reported.
- Lack or loss of appetite, inflammation of the tongue and difficulty in swallowing.
- Inflammation and/or ulcers of the gullet (food pipe). This can be avoided by taking Periostat in an upright position with water (see Section 3 How to take Periostat).
- Increase in blood urea (this is detected by a blood test).
- If you suffer from a disease called systemic lupus erythematosus (SLE), an allergic condition which causes joint pain, skin rashes and fever you may notice your condition gets worse.
- Severe headaches together with disturbed vision. This may mean you have increased pressure in the brain
- Problem with your liver (this may cause yellowing of the skin or whites of the eyes and/or severe stomach pains) (see Section 2 What you need to know before you take Periostat).
- Stevens-Johnson syndrome (a serious illness which causes blistering of the skin, lining of the mouth, throat, eyes and genitals), flaking or peeling of the skin.

### **Reporting of side effects**

If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Periostat**

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

Do not use Periostat after the expiry date {EXP mm yyyy} which is stated on the white container or blister pack. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not remove the tablets from the container or blister pack until you are ready to take the medicine. When tablets are supplied in a white container, always ensure the desiccant is returned to the container, and the container tightly closed after each dose is removed. Do not swallow the desiccant, and should this occur, contact your dentist or doctor immediately.

Do not take Periostat if you notice the appearance of the tablets has changed in any way.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Periostat contains**

The active ingredient in this medicine is doxycycline hyclate.

Each tablet contains 23.08 mg doxycycline hyclate equivalent to 20 mg doxycycline. The other ingredients are:

- tablet core: microcrystalline cellulose, magnesium stearate
- film-coating: lactose monohydrate, hypromellose (E464), titanium dioxide (E171) and triacetin.

### **What Periostat looks like and contents of the pack**

Periostat tablets are white to off-white round tablets imprinted on one side with PS-20.

Periostat tablets are supplied in either blister packs contained in a carton (28 or 56 tablets) or in a white container, with a child resistant closure (60 tablets). Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is: Alliance Pharmaceuticals Limited, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Periostat is manufactured by: Chanelle Medical, Loughrea, Co. Galway, Ireland.

The information in this leaflet applies only to Periostat. If you have any questions or you are not sure about anything, ask your dentist, doctor or a pharmacist.

**This leaflet was last revised:** August 2020

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