

**Pyostacine® 500 mg film-coated tablet****Pristinamycin**

**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. See section 4.

**What is in this leaflet**

1. What PYOSTACINE 500 mg film-coated tablet is and what it is used for.
2. What you need to know before you take PYOSTACINE 500 mg film-coated tablet.
3. How to take PYOSTACINE 500 mg film-coated tablet.
4. Possible side effects.
5. How to store PYOSTACINE 500 mg film-coated tablet.
6. Contents of the pack and other information.

**1. What PYOSTACINE 500 mg film-coated tablet is and what it is used for**

Pharmacotherapeutic class: streptogramins (synergistins) – ATC code: J01FG01.

This medication is an antibiotic from the streptogramin family (synergistins). The active substance is pristinamycin. It acts by killing the bacteria that cause infections. It works on certain bacteria.

This medication is indicated in adults and children for treating the following bacterial infections:

- respiratory infections: certain ENT infections, acute exacerbations of chronic bronchitis, pneumonia,
- infections of the skin and soft tissue.

**2. What you need to know before you take PYOSTACINE 500 mg film-coated tablet****Do not take PYOSTACINE 500 mg film-coated tablet:**

- if you are allergic to pristinamycin, other synergistins or any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to wheat, due to the presence of wheat starch,
- if you have a history of severe pustular rash or other rash when taking this medicine (see section "Warnings and precautions"),
- if you are breast-feeding (see section "Pregnancy and breast-feeding"),
- in conjunction with colchicine (medication used to treat gout).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking PYOSTACINE 500 mg film-coated tablet.

Talk to your doctor before taking this medication if you have had an allergic reaction with previous antibiotic medication: hives or other skin rash, itching, sudden swelling of the face and neck which may cause breathing problems (Quincke's oedema).

Tell your doctor immediately if during treatment you notice blistering (peeling skin and mucous membranes, especially in the mouth, nose, genital areas) which may spread over the entire body or the appearance of a severe skin rash possibly combined with other symptoms such as fever, enlarged lymph glands, extreme tiredness, liver or kidney disorder (see section 4. "Possible side effects").

Tell your doctor if you have already taken a virginiamycin-based medication.

**Children**

See section 3 "Use in children".

**Other medicines and PYOSTACINE 500 mg film-coated tablet**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This applies particularly to oral anticoagulants known as anti-vitamin K drugs which are prescribed to

prevent blood clots or immunosuppressants which are used to reduce the body's immune reactions.

PYOSTACINE 500 mg film-coated tablet should never be taken at the same time as a medicine containing colchicine used to treat painful, swollen joints associated with an excess of uric acid (gout).

**Pregnancy and breast-feeding**

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

**Pregnancy**

This medicine should only be used during pregnancy upon the advice of your doctor.

If you discover that you are pregnant during treatment, consult your doctor because only he can assess the need to continue taking it.

**Breast-feeding**

Do not use this medicine if you are breast-feeding.

**PYOSTACINE 500 mg film-coated tablet contains gluten**

This medication contains a very low content of gluten (derived from wheat starch) and is therefore unlikely to cause problems in coeliac disease.

One tablet contains no more than 70.0 micrograms of gluten.

If you have a wheat allergy (different from coeliac disease), you should not take this medication (see section "Do not take PYOSTACINE 500 mg, film-coated tablet").

**3. How to take PYOSTACINE 500 mg film-coated tablet**

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

Your doctor will tell you exactly how much PYOSTACINE 500mg film-coated tablet you should take, how often and for how long. This will depend on the type of infection and how severe it is.

**Dosage**

The dosage depends on the age of the patient and the infection being treated.

As a guideline, the prescribed doses may vary:

- Adults: 2-4 g a day.
- Children (dose expressed according to the weight of the child): 50 mg/kg/day, or 100 mg/kg/day but not exceeding the adult dose.

Your doctor might start treatment at the highest dose.

**Method of administration**

For oral use.

Take with meals.

Swallow the tablets with fluid.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

**Use in children**

Pristinamycin is also available in a 250 mg tablet which may be more suitable in some cases, especially for children.

Children aged under 6 years should not take tablets as they may choke. There are no pristinamycin-based products specifically for young children.

To administer to young children, crush the tablets in a little milk or a sweet base (jam).

**Frequency of administration**

Two or three times a day.

**Length of treatment**

To be effective, this antibiotic should be used regularly at the prescribed doses and for as long as advised by your doctor.

Disappearance of fever or any other symptom does not mean that you are completely cured.

Any feeling of tiredness is not due to the antibiotic treatment but to the infection itself. The fact of reducing or suspending your treatment would have no effect on this feeling and would delay your recovery.

**If take more PYOSTACINE 500 mg film-coated tablet than you should**

In the event of an overdose, the aim of any prescribed treatment will be to treat your symptoms. Consult your doctor or pharmacist immediately.

**If you forget to take PYOSTACINE 500 mg film-coated tablet**

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

**4. Possible side effects**

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

**Contact your doctor immediately if you develop an allergy or a severe skin reaction (see section 2 "Do not take PYOSTACINE 500 mg film-coated tablet" and "Warnings and precautions").**

This medicine may cause an allergic reaction such as:

- Uncommon (may affect up to 1 in 100 people):
  - urticaria (red, itchy patches on the skin).
- Not known (frequency cannot be estimated from the available data):
  - Quincke's oedema (sudden swelling of the neck and face which may cause breathing problems)
  - anaphylactic shock (severe allergic reaction endangering the patient and involving feeling suddenly unwell with a sharp fall in blood pressure which may be preceded by a spotty rash, itching, red patches on the skin, breathing problems, swelling of the face and/or neck).

This medicine may also cause severe, potentially fatal skin disorders, especially:

- Not known (frequency cannot be estimated from the available data):
  - blisters on the skin,
  - the appearance of fluid-filled sacs, blisters or peeling skin, especially around the mouth, nose, eyes and genital area (Lyell's syndrome, Stevens-Johnson syndrome),
  - a skin rash which may be accompanied by fever, with sudden onset and starting on the face or in skin folds and which may spread over the entire body (acute generalised exanthematous pustulosis),
  - a severe allergic reaction (drug rash with eosinophilia and systemic symptoms (DRESS)) possibly combined with a number of symptoms such as fever, skin rash, enlarged lymph glands, severe tiredness, liver or kidney disorder and abnormal blood tests such as a rise in a specific white cell count (eosinophils).

If any of these side effects occur, stop taking the medicine and contact your doctor immediately. You should not be prescribed this medicine again in future.

**Contact your doctor immediately if you develop severe gastrointestinal problems such as:**

- Common (may affect up to 1 in 10 people):
  - acute inflammation of the colon accompanied by blood in stools (acute haemorrhagic colitis).
- Not known (frequency cannot be estimated from the available data):
  - acute inflammation of the colon characterised by diarrhoea which may contain blood and be caused by *Clostridium difficile* infection (pseudo-membranous colitis)

If any of these side effects occur, stop taking the medication and contact your doctor immediately.

**Other side effects**

If you experience any of the following side effects, talk to your doctor or pharmacist:

- Very common (may affect more than 1 in 10 people):
  - possible bloated stomach,
  - vomiting.
- Common (may affect up to 1 in 10 people):
  - diarrhoea (with abdominal pain),
  - nausea,
  - skin rash.
- Not known (frequency cannot be estimated from the available data):

- skin problem which may be exacerbated by itching, redness and a burning sensation (eczema),
- small red marks on the skin (vascular purpura),
- decrease in the number of platelets in the blood (thrombocytopenia),
- decrease in the number of white blood cells in the blood (leukopenia),
- decrease in the number of certain white blood cells in the blood which may be significant (agranulocytosis, neutropenia),
- reduction in white and red blood cells and platelets (pancytopenia),
- reduced kidney function (acute renal failure),
- hallucinations,
- liver dysfunction.

**Reporting side effects**

If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (in France) via the national registration system: The National Agency for the Safety of Medicines and Health Products (ANSM) and Regional Drug Safety Centres network.

Website: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr).

By reporting side effects, you may help to provide more information on the safety of this product.

**5. How to store PYOSTACINE 500 mg film-coated tablet**

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton.

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 protect the environment.

**6. Contents of pack and other information****What PYOSTACINE 500 mg film-coated tablet contains**

- The active substance is:
  - Pristinamycin (at 8000 UI/mg).....500 mg per film-coated tablet.
- The other ingredients are:
  - Colloidal hydrated silica, white dextrin, gelatin, magnesium stearate, wheat starch, hypromellose, macrogol 6000, titanium dioxide.

**What PYOSTACINE 500 mg film-coated tablet looks like and contents of the pack:**

This medicinal product comes in the form of coated tablets. Pack of 16 or 100.

**Marketing Authorisation Holder and Operator**

Sanofi-Aventis France  
82, avenue Raspail  
94250 Gentilly  
France

If you have any questions about this product or if you wish to report an adverse effect to us, consult the "Our medicines" section on the website [www.sanofi.fr](http://www.sanofi.fr) or contact us by telephone:

Patient information: 0800222555 Free Service and Call.  
Call from abroad: +33157632323

**Manufacturer**

Sanofi S.r.l  
Strada Statale 17, km 22  
67019 Scoppito (AQ)  
Italy

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**Other sources of information**

Detailed information on this medicine is available on the ANSM website (France)

**ADVICE / HEALTH EDUCATION****WHAT DO YOU NEED TO KNOW ABOUT ANTIBIOTICS?**

Antibiotics are effective in combating infections caused by bacteria. They are not effective against infections caused by viruses.

Your doctor has also opted to prescribe you this antibiotic because it is suitable for your specific case and your current illness.

Bacteria are able to survive or reproduce despite the action of an antibiotic. This phenomenon is called resistance. It makes some antibiotic medications ineffective.

Resistance increases if antibiotics are abused or used inappropriately.

You risk encouraging the development of resistant bacteria and thereby delaying your recovery or even rendering this medicine ineffective, if you do not adhere to:

- the prescribed dose,
- the correct times to take it,
- and the correct length of treatment.

**To maintain the efficacy of this medicine, therefore:**

- 1. Only use an antibiotic when prescribed by your doctor.**
- 2. Adhere strictly to your prescription.**
- 3. Do not use an antibiotic again unless prescribed by your doctor even if you think you are combating an apparently similar illness.**
- 4. Never give your antibiotic to someone else. It may not be suitable for their illness.**
- 5. Once your treatment is complete, return any opened packs to your pharmacist who will dispose of this medicine correctly and appropriately.**

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