

# AVEXUS FILM-COATED TABLET

Clarithromycin (250mg,500mg)

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## What Avexus is used for

It is used to treat bacterial infection in respiratory tract, skin, soft tissue and ear.

Used in combination with other medicines to treat gastrointestinal tract infection caused by *H. pylori*, a common bacteria found in stomach.

## How Avexus works

Clarithromycin is the antibiotic which inhibits bacteria from producing proteins that are essential for their growth in human body.

## Before you use Avexus

### -When you must not use it

Do not use Avexus if you are:

- allergic to clarithromycin or any other ingredients in this medicine. Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.
- Concomitant administration of Avexus with:
  1. cisapride, a medicine used to treat stomach disorders
  2. pimozide, a medicine used to treat psychotic disorders
  3. astemizole or terfenadine, medicine for allergic reaction
- Do not take Avexus if you are taking domperidone (used for nausea & vomiting)

### -Before you start to use it

Tell your doctor or pharmacist before using Avexus if you:

- are pregnant or plan to pregnant.
- are breast-feeding or plan to start breast-feeding.
- have liver dysfunction.
- have kidney disease.
- are elderly

- have arrhythmia (irregular or slow heart beat)

Please kindly consult your doctor before start to use Avexus if your child is less than 6 months of age.

### -Taking other medicines

Tell your doctor or pharmacist if you are taking or having recently taken any other medicines. This includes any medicines which you have bought without a prescription.

## How to use Avexus

### -How much to use

#### Adults

- 250mg every 12 hours for 7 days
- For severe infections: 500mg every 12 hours for 14 days
- For *H. pylori* treatment: 500mg every 12 hours for 7 to 14 days

Children: a course is usually for 10 days

- Body weight under 8kg: 7.5mg/kg, twice daily
- 7-9 years old; 20-29kg: 187.5mg, twice daily
- 10-12 years old; 30-40kg: 250mg, twice daily

Triple therapy: a course for 10 days

500mg Clarithromycin (twice daily) + 1000mg Amoxycillin (twice daily) + 20mg Omeprazole (once daily).

### -When to use it

With or without food.

Follow the prescription from your doctor or pharmacist.

### -How long to use it

Follow the prescription from your doctor or pharmacist. Ask your doctor or pharmacist before prolonged use of this medicine.

Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

### -If you forget to use it

Use it as soon as you remember, unless it is nearly time for your next dose, skip the missed dose. Then go on as before. Never double up on the next dose to make up for the one missed.

### -If you use too much (overdose)

Overdose may result in abdominal pain, vomiting, nausea and diarrhoea.

Seek immediate medical attention if you have used too much or are worried with your condition.

## While you are using it

### -Things you must do

- Always wash your hand before handle the medicine. Swallow the tablets with water and take it at the same time each day.
- If you develop severe or persistent diarrhea during or after taking Avexus, consult your doctor immediately.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Avexus.
- Tell your doctor immediately if you become pregnant while taking this medication.

### -Things you must not do

- Do not chew the medicine. Swallow it with water.
- Do not use this medicine by yourself without prescription from your doctor or pharmacist.
- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Avexus to anyone else, even if they have the same symptoms or condition as you.

### -Things to be careful of

Be careful driving or operating machinery until you know how Avexus affects you.

## Side effects

- Diarrhoea, nausea, indigestion, abdominal pain, heartburn
- Smell and taste disturbances
- Tongue inflammation
- Loss of appetite
- Low blood sugar
- Hearing loss
- Blood disorder
- Headache, dizziness, insomnia
- Skin rashes, itchiness and skin reaction e.g. Stevens-Johnson syndrome and toxic epidermal necrolysis
- Jaundice, hepatitis
- Behavioral change

Avexus may cause severe allergy and serious skin reaction. Stop using Avexus and seek medical assistance immediately if you experience any of the following symptoms:

- Skin reddening, blisters, rash, fever, sore throat or eye irritation

Seek immediate medical attention if you experience any side effects or allergic reactions. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nppra.gov.my](http://nppra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of Avexus

#### -Storage

Store below 30°C.

Keep out of the reach of the children.

Do not use this medicine after expiry date.

#### -Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

### Product Description

#### -What it looks like

*Avexus Film-Coated Tablet 250mg:*

Yellow, oval-shape, film-coated tablet with “XS” marking on one side and plain on the other side.

*Avexus Film-Coated Tablet 500mg:*

Light yellow, oval shape, film-coated tablet with logo on one side and plain on the other side.

#### -Ingredients

-Active ingredient

Clarithromycin

-Inactive Ingredients

*Avexus Film-Coated Tablet*

*250mg:*

Sodium Starch Glycolate,  
Quinoline Yellow Lake, Maize  
Starch, HPCM Compound Mix,  
Dioctyl Sodium Sulfosuccinate,  
Purified Water, Aerosil 200,  
Isopropyl Alcohol, Magnesium  
Stearate, Lactose 200 Mesh, PVP-  
K30, Microcrystalline Cellulose.

*Avexus Film-Coated Tablet*

*500mg:*

Sodium Starch Glycolate,  
Quinoline Yellow Lake, Maize  
Starch, HPCM Compound Mix,  
Dioctyl Sodium Sulfosuccinate,  
Purified Water, Aerosil 200,  
Isopropyl Alcohol, Magnesium  
Stearate, PVP-K30.

#### -MAL Number:

*Avexus Film-Coated Tablet 250mg:*

MAL04091676AZ

*Avexus Film-Coated Tablet 500mg:*

MAL04091677AZ

### Manufacturer and Product Registration Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd

1-5 Cheng Industrial Estate,

75250 Melaka, Malaysia.

#### **Date of revision**

08/07/2020

#### **Serial number**

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