

PATIENT INFORMATION LEAFLET
(PIL)

**PATIENT INFORMATION LEAFLET:
INFORMATION FOR THE USER
SPOTCLAV 625**

Amoxicillin 500 mg/clavulanic acid 125 mg

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider

In this leaflet

- a) What Spotclav is and what it is used for
- b) What you need to know before you take Spotclav
- c) How to take Spotclav
- d) Possible side effects
- e) How to store Spotclav
- f) Further information

a) What Spotclav is and what it is used for

Spotclav is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillins” that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Spotclav is used in adults and children to treat the following infections:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections
- Bone and joint infections in particular osteomyelitis.

b) What you need to know before you take Spotclav

Do not take Spotclav :

- if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine.
 - Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents.
- Do not take Spotclav if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking Spotclav.

Take special care with Spotclav:

Talk to your doctor or pharmacist before taking Spotclav if you:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Spotclav.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Spotclav or a different medicine.

Spotclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Spotclav, to reduce the risk of any problems.

Blood and urine tests

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Spotclav. This is because Spotclav can affect the results of these types of tests.

Other medicines and Spotclav

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

If you are taking allopurinol (used for gout) with Spotclav, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Spotclav.

If medicines to help stop blood clots (such as warfarin) are taken with Spotclav then extra blood tests may be needed.

Spotclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Spotclav can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Taking Spotclav with food and drinks

Swallow the tablets whole with a glass of water at the start of a meal or slightly before.

Pregnancy, breast-feeding and fertility

Use should be avoided during pregnancy, unless considered essential by the physician.

Amoxicillin/clavulanic acid should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

Driving and using machines

Spotclav can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

c) How to take Spotclav

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

Adults and children weighing 40 kg and over

- Usual dose – 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Spotclav oral suspension or sachets. Ask your doctor or pharmacist for advice when giving Spotclav tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

How to take Spotclav

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Spotclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Spotclav than you should

If you take too much Spotclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

If you forget to take Spotclav

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Spotclav

Keep taking Spotclav until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

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

d) Possible side effects

Like all medicines, Spotclav can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- skin rash
 - inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
 - fever, joint pain, swollen glands in the neck, armpit or groin
 - swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
 - collapse.
- Contact a doctor immediately** if you get any of these symptoms. **Stop taking Spotclav.**

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Contact your doctor as soon as possible for advice if you get these symptoms.

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses
→if affected take Spotclav before food
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in your blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – *erythema multiforme*)
- if you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

Frequency not known

Frequency cannot be estimated from the available data.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).
 - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Contact a doctor immediately if you get any of these symptoms.**
 - inflammation of the liver (*hepatitis*)
 - jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
 - inflammation of tubes in the kidney
 - blood takes longer to clot

- hyperactivity
- convulsions (in people taking high doses of Spotclav or who have kidney problems)
- black tongue which looks hairy

Side effects that may show up in your blood or urine tests:

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

e) How to store Spotclav

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a cool, dry place. Protect from light. Store Below 30° C. Keep all Medicines out of reach of children.

Store in the original package in order to protect from moisture.

Do not use if the tablets are chipped or damaged.

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

f) Contents of the pack and further information

What Spotclav contains

- The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid.
- The other ingredients are: Tablet core - Microcrystalline Cellulose, Sodium Starch Glycolate, Croscarmellose Sodium, Dibasic Calcium Phosphate (Anhydrous), Magnesium Stearate
Film coat - Coating Premix White, Ethyl Cellulose, Diethyl phthalate, Isopropyl alcohol
Dichloromethane

What Spotclav looks like and contents of the pack

Spotclav 625 film-coated tablets are White Coloured, elongated shaped, biconvex, film coated tablet having plain surface on both sides.

They are packaged in:

- 2 Alu-Alu Blisters of 10 Tablets packed in an aluminum pouch with silica gel, which is further packed in a Carton with leaflet

Name and full physical address of Marketing Authorisation Holder and Manufacturing site:

Name : Sparsh Bio-Tech Private Limited
Address : Plot No. 1; Survey No. 242/243/244, Lakhavad, Jamnagar-361 006, India
Phone : + 91-288-2889032/33/34
E-mail : sushant@sparshbiotech.com, info@sparshbiotech.com

For any information about this medicinal product, please contact the local representative of the supplier:

Name : ABACUS PHARMA (A) LTD.
Address : Kigali City Market, B1-R85, PO Box 4344 Kigali, RWANDA
Phone : +250 252 502973
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