

NEW ZEALAND CONSUMER MEDICINE INFORMATION

STAPHLEX



Flucloxacillin (as the sodium salt) 250 mg and 500 mg Capsules

What is in this leaflet

This leaflet answers some common questions about STAPHLEX.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking STAPHLEX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What STAPHLEX is used for

STAPHLEX contains the active ingredient flucloxacillin. STAPHLEX is an antibiotic that belongs to a group of medicines called penicillins. These medicines work by killing the bacteria that are causing your infection.

STAPHLEX is used to treat infections in different parts of the body caused by bacteria. Examples of some of the infections that may be caused by bacteria include respiratory tract infections, and skin or fleshy tissue skin infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

STAPHLEX will not work against infections caused by viruses, such as colds or the flu.

STAPHLEX is available only with a doctor's prescription.

There is no evidence that STAPHLEX is addictive.

Before you take STAPHLEX

When you must not take it

Do not take STAPHLEX if you have an allergy to:

- medicines containing flucloxacillin or any other penicillin
- beta-lactam antibiotics including cephalosporin antibiotics
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take STAPHLEX if you have had a reaction that has affected your liver while you were taking a medicine containing flucloxacillin. Examples of liver reactions include hepatitis and jaundice (yellowing of the eyes or skin).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

This medicine may cause undesirable effects (e.g. allergic reactions, dizziness) which may influence the ability to drive and use machines. Patients should be cautious when driving or operating machinery.

If you have not told your doctor about any of the above, tell him/her before you start taking STAPHLEX.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and STAPHLEX may interfere with each other. These include:

- probenecid, a medicine used for gout
- some antibiotics, such as tetracycline and macrolide antibiotics.
- oral typhoid vaccine

- sugammadex, a medicine used in correction with surgery
- warfarin, a blood thinning medicine
- methotrexate, a medicine used for treating some cancers and psoriasis
- paracetamol, a medicine used for pain and fever.

These medicines may be affected by STAPHLEX or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Talk to your doctor about the need for additional contraception while taking STAPHLEX. Some antibiotics may decrease the effectiveness of some birth control pills. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take STAPHLEX

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much you need to take each day and when to take it. This depends on your condition and whether or not you are taking any other medicines.

The usual adult dose is 250mg every 6 hours however this will depend on the severity of the infection.

If you have kidney problems, your doctor may tell you to take a lower dose.

How to take it

Take STAPHLEX on an empty stomach, for example, one hour

before food or two hours after food.

Food can interfere with the absorption of STAPHLEX.

Swallow the capsules whole with a glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking STAPHLEX until you finish the course, or for as long as your doctor tells you.

Do not stop taking STAPHLEX, even if you feel better after a few days, unless advised by your doctor. If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much STAPHLEX. Do

this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting and diarrhoea.

While you are using STAPHLEX

Things you must do

If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you develop jaundice (yellowing of the eyes or skin), tell your doctor immediately. Do this even if it occurs several weeks after you have stopped taking STAPHLEX.

Jaundice may mean that you have a serious condition affecting your liver. You may need urgent medical care.

If you get severe diarrhoea, tell your doctor or pharmacist immediately.

Severe diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you become pregnant while you are taking STAPHLEX tell your doctor immediately.

Before starting any new medicine, tell your doctor or pharmacist that you are taking STAPHLEX.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking STAPHLEX.

If you have to have any blood tests tell your doctor you are taking STAPHLEX. STAPHLEX may affect the results of some blood tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests (such as blood and renal function tests) from time to time to make sure the medicine is working and to

prevent unwanted side effects, especially if you are using this medicine long term.

Things you must not do

Do not take STAPHLEX to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking STAPHLEX, even if you feel better after a few days, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Side effects

IMPORTANT: Flucloxacillin can cause severe liver damage, which can make the skin and whites of the eyes turn yellow in colour (jaundice). This is more likely to occur in older patients and those who take it for more than 14 days. Immediately contact your doctor if you notice any yellowing of your eyes or skin.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking STAPHLEX.

STAPHLEX treats infections in most people, but it may cause side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling sick or vomiting

- stomach upset, diarrhoea
- painful and/or swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- oral thrush (white, furry sore tongue and/or mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge).

The above list includes the more common side effects of your medicine. They are usually mild and your doctor or pharmacist will be able to give you advice.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- yellowing of the eyes or skin (jaundice)
- skin lesions or pustules
- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- dark or cloudy urine, blood in the urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

If any of the following happen, stop taking STAPHLEX and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or troubled breathing.

If you experience any of these side effects, you may have had a serious allergic reaction to STAPHLEX. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using STAPHLEX

Storage

Keep your medicine in the pack until it is time to take it.

If you take medicine out of the pack it may not keep well.

Store STAPHLEX capsules in a cool dry place where the temperature stays below 25°C.

Do not store STAPHLEX or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

STAPHLEX capsules are available as either a 250 mg and 500 mg capsule.

STAPHLEX 250 mg and 500 mg capsules have a yellow body and black cap.

Ingredients

The active ingredient in STAPHLEX is flucloxacillin (as the sodium salt).

Each Staphlex 250 capsule contains 250 mg (milligrams) of flucloxacillin (as the sodium salt).

Each Staphlex 500 capsule contains 500 mg of flucloxacillin (as the sodium salt).

The capsules also contain:

- Povidone
- Talc
- Sodium starch glycollate
- Microcrystalline cellulose
- Magnesium stearate
- Gelatin
- Titanium Dioxide
- FD&C Blue 1
- Red Iron Oxide
- Yellow Iron Oxide.

The capsules are gluten and lactose free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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