

This product is no longer marketed in New Zealand and this consumer medicine information may not be up to date. More up-to-date consumer medicine information for a product with the same active ingredient may be available on the Medsafe website.

## STAPHLEX

*Flucloxacillin, as the sodium salt*



### What is in this leaflet

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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 using STAPHLEX against the benefits they expect it will have for you. If you have concerns about using this medicine ask your doctor or pharmacist. Keep this leaflet. You may need to read it again.

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### What STAPHLEX is used for and how it works

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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.

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.

Your doctor however, may have prescribed STAPHLEX for another reason. Ask your doctor if you have any questions about why STAPHLEX has been prescribed for you.

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.

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### Before you take STAPHLEX

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#### ***When you must not take STAPHLEX:***

**Do not take STAPHLEX if you are allergic 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 skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

**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 STAPHLEX if the packaging is torn or shows signs of tampering.

**Do not take STAPHLEX if the expiry date (EXP) printed on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work as well.

## ***Before you start to take it***

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have any medical conditions, especially the following:**

- liver problems
- kidney problems

**Tell your doctor if you are pregnant or plan to become pregnant.** Your doctor will discuss the risks and benefits of taking STAPHLEX during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.** A very small quantity of STAPHLEX passes into breast milk. Your doctor will discuss the risks and benefits of taking STAPHLEX when breastfeeding.

**If you have not told your doctor about any of the above, tell them before you take STAPHLEX.**

## ***Taking other medicines***

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

**Some medicines that may interfere with STAPHLEX include:**

- probenecid, a medicine used for gout
- bacteriostatic antibiotics, such as tetracycline and macrolide antibiotics.

These medicines may be affected by STAPHLEX or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

**Talk to your doctor about the need for additional contraception while taking STAPHLEX.** Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with STAPHLEX.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking STAPHLEX.

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## **How to take STAPHLEX properly**

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### ***How much to take***

**Follow all directions given to you by your doctor carefully.**

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 250-500mg every 8 hours however this will depend on the severity of the infection.

For children, their doctor will work out the dose according to their age and how severe the infection is.

### ***How to take STAPHLEX***

**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.**

### ***How long to take STAPHLEX***

**Keep taking STAPHLEX until you finish the pack, or for as long as your doctor recommends.**

**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 STAPHLEX***

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 the missed dose as soon as you remember, and then go back to taking your capsules as you would normally.

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

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

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## **While you are taking Staphlex**

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### ***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.**

**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.

### ***Things you must not do***

**Do not use STAPHLEX to treat any other conditions unless your doctor tells you to.**

**Do not give STAPHLEX 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.

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## Side effects

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**IMPORTANT: Flucloxacillin can cause severe liver damage, which can make the skin and whites of the eyes turn yellow in colour. 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.

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

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

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

These side effects are usually mild and short-lived.

**Tell your doctor immediately, or go to accident and emergency at the nearest hospital if you notice any of the following:**

- yellowing of the eyes or skin (jaundice)
- 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.

These may be signs of rare but serious side effects of STAPHLEX. You may need urgent medical attention.

**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.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## **In case of overdose**

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**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any STAPHLEX by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of STAPHLEX with you if you can.**

Keep telephone numbers for these places handy.

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## **After taking STAPHLEX**

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### ***Storage***

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

**Keep STAPHLEX where children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground are a good place to store medicines.

**Keep STAPHLEX syrup in the refrigerator but not in the freezer.**

**Do not use any syrup left in the bottle after 14 days.**

**Do not store STAPHLEX or any other medicine in the bathroom or near a sink.**

**Do not leave STAPHLEX in the car or on windowsills.** Heat and dampness can destroy some medicines.

### ***Disposal***

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

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## **Product Description**

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### ***What it looks like***

STAPHLEX is available in capsules. STAPHLEX syrup is not marketed.

STAPHLEX capsules come in two strengths: STAPHLEX 250 and STAPHLEX 500.

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 of flucloxacillin (as the sodium salt).

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

The capsules also contain:

- Povidone PVPK 30
- 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.

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## **If you want to know more**

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

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
P O Box 11183,  
Ellerslie,  
Auckland.

Telephone: 09 579 2792

### ***Date of information***

8 October 2009  
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