

Staphylex

flucloxacillin (as sodium monohydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Staphylex.

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

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

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

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

What Staphylex is used for

Staphylex contains flucloxacillin (flucloxacillin sodium monohydrate) as the active ingredient.

Staphylex is used to treat infections in different parts of the body caused by bacteria.

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

Staphylex is an antibiotic that belongs to a group of medicines called penicillins. These medicines work by killing the bacteria that are causing your infection.

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

Staphylex is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take Staphylex

WARNING: Flucloxacillin sodium monohydrate can cause severe liver damage, particularly in older patients and those who take it for more than 14 days.

When you must not take Staphylex

Do not take Staphylex if you are allergic to:

- medicines containing flucloxacillin or any other penicillin
- cephalosporin antibiotics
- beta-lactam antibiotics including imipenem and aztreonam
- 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 Staphylex if you have had a reaction affecting your liver while you were taking a medicine containing Flucloxacillin sodium monohydrate.

Examples of liver reactions include hepatitis and jaundice (yellowing of the eyes or skin).

Do not take Staphylex if the expiry date (Exp.) printed on the pack has passed.

Do not take Staphylex if the packaging shows signs of tampering or the capsules do not look quite right.

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

Do not give this medicine to anyone else.

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 are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Staphylex during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Staphylex passes into breast milk. Your doctor will discuss the risks and benefits of taking Staphylex when breastfeeding.

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

- liver problems
- kidney problems
- jaundice, yellowing of the skin or eyes
- asthma, hayfever, eczema or other allergic conditions.

If you have not told your doctor about any of the above, tell them before you start taking Staphylex.

Taking other medicines

Tell your doctor or pharmacist if you are taking this medicine in combination with paracetamol, particularly if you have impaired kidney function.

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 may be affected by Staphylex, or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking Staphylex with other medicines, such as probenecid, a medicine commonly used to treat gout. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid whilst taking this medicine.

Talk to your doctor about the need for additional contraception while taking Staphylex.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Staphylex.

How to take Staphylex

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.

For most infections, the usual dose for adults is 250 mg every 6 hours.

Follow all directions given to you by your doctor carefully.

How to take Staphylex

Swallow the capsules with a glass of water.

Take Staphylex on an empty stomach, for example, half to one hour before meals and at bedtime.

Food can interfere with the absorption of Staphylex.

If you forget to take Staphylex

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 tablets 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.

How long to take Staphylex for

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

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

If you take too much Staphylex (overdose)

Telephone your doctor or the Poisons Information Centre (telephone 13 11 26), if you think you or anyone else may have taken too much Staphylex. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Staphylex, you may get diarrhoea and nausea.

While you are taking Staphylex

Things you must do

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

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

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 Staphylex.

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. Do this even if it occurs several weeks after you have stopped taking Staphylex.

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 checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping Staphylex, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes, the use of Staphylex allows fungi to grow and the

above symptoms to occur. Staphylex does not work against fungi.

If you get severe skin reactions with painful red areas, large blisters, peeling of skin layers; fever, chills, aching muscles, feeling unwell (signs of drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome or toxic epidermal necrolysis). Stop taking this medicine immediately and tell your doctor.

If you are on a sodium restricted diet, it is recommended that you seek advice from your doctor or pharmacist to include the sodium content of Staphylex in your daily sodium allowance.

If you are taking Staphylex for a long time, visit your doctor regularly so that they can check on your progress.

You may need to have tests to check your liver and kidney function.

Things you must not do

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

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

Things to be careful of

As with any new medicine, you should take care when driving or operation machinery until you know how Staphylex affects you as it may cause dizziness, drowsiness or tiredness in some people.

Side effects

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

Staphylex treats infections in most people, but it may have unwanted 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.

IMPORTANT: Flucloxacillin sodium monohydrate 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.

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

While you are taking Staphylex

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

- feeling sick or vomiting
- stomach upset, diarrhoea
- a mild rash
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina and/or vaginal discharge).

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps

- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal
- frequent infections such as fever, chills, sore throat or mouth ulcers
- yellowing of the eyes or skin (jaundice)
- painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- irregular heart beat
- dark or cloudy urine, blood in the urine.

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

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

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

These include very rare conditions such as blood, liver, and kidney problems or fits.

After you have finished taking Staphylex

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with Staphylex:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- yellowing of the eyes or skin (jaundice).

These are rare but serious side effects. Staphylex can change bacteria (which are normally present in the bowel and normally harmless) to multiply and therefore cause the above symptoms. You may need urgent medical attention.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Staphylex

Storage

Keep Staphylex 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.

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

Do not keep Staphylex or any other medicine in the bathroom or near a sink.

Do not leave Staphylex in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Staphylex, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Staphylex comes in two strengths: Staphylex 250 and Staphylex 500.

Both are yellow and black capsules.

Each pack contains 24 capsules.

Ingredients

The active ingredient in Staphylex is flucloxacillin (as flucloxacillin sodium monohydrate).

- each Staphylex 250 capsule contains 250 mg of flucloxacillin (as sodium monohydrate)
- each Staphylex 500 capsule contains 500 mg of flucloxacillin (as sodium monohydrate).

The capsules also contain:

- povidone
- purified talc
- sodium starch glycolate
- microcrystalline cellulose
- magnesium stearate
- sodium lauryl sulfate
- colloidal anhydrous silica
- gelatin
- yellow Opaque size 0 (PI 12223)
- yellow Opaque size 2 (PI 12364)

Supplier

Staphylex is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Staphylex 250 - Aust R 17683

Staphylex 500 - Aust R 17684

This leaflet was prepared on

9 April 2019.