Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Flucloxacillin Kabi?

Flucloxacillin Kabi contains the active ingredient flucloxacillin sodium monohydrate. Flucloxacillin Kabi, belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria causing your infection.

For more information, see Section <u>1. Why am I using Flucloxacillin?</u> in the full CMI.

2. What should I know before I am given Flucloxacillin Kabi?

Do not use if you have ever had an allergic reaction to flucloxacillin or other penicillin's or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given Flucloxacillin Kabi? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Flucloxacillin Kabi and affect how it works.

A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How am I given Flucloxacillin Kabi?

Flucloxacillin Kabi will be given to you by a doctor or nurse. Your doctor will decide what dose and how long you will receive Flucloxacillin Kabi for. This depends on your infection and other factors, such as your weight. For most infections, Flucloxacillin Kabi is usually given in divided doses throughout the day.

More instructions can be found in Section <u>4. How am I given Flucloxacillin Kabi?</u> in the full CMI.

5. What should I know after receiving Flucloxacillin Kabi?

Things you	• Remind any doctor, dentist or pharmacist you visit that you are using Flucloxacillin Kabi.
should do	 If symptoms of your infection do not improve within a few days, or if they become worse tell your doctor.
	If you develop itching with swelling or skin rash or difficulty breathing while you are receiving
	Flucloxacillin Kabi, do not have any more and tell your doctor immediately.
	• If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Flucloxacillin Kabi has been stopped.
	 Do not take any diarrhea medicine without first checking with your doctor
	• If you get a sore white mouth or tongue while being treated with or soon after stopping Flucloxacillin Kabi, tell your doctor.
	 Also tell your doctor if you get vaginal itching or discharge.

For more information, see Section 5. What should I know after receiving Flucloxacillin Kabi? in the full CMI.

6. Are there any side effects?

Side effects include pain or redness at the site of injection, mild rash, oral thrush, vaginal thrush, nausea, stomach upsets, mild diarrhoea, constipation, dizziness or headaches.

Like other medicines, Flucloxacillin Kabi can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

If you are over 65 years of age you may have an increased chance of getting side effects.

You may not experience any of them.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Flucloxacillin Kabi

Active ingredient(s): Flucloxacillin sodium monohydrate

(floo-klox-s-SILL-in)

Consumer Medicine Information (CMI)

This leaflet answers some common questions about Flucloxacillin Kabi. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Flucloxacillin Kabi.

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 Flucloxacillin Kabi 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 in a safe place.

You may need to read it again

Where to find information in this leaflet:

1. Why am I being given Flucloxacillin Kabi?

2. What should I know before I am given Flucloxacillin Kabi?

- 3. What if I am taking other medicines?
- 4. How am I given Flucloxacillin Kabi?
- 5. What should I know after receiving Flucloxacillin Kabi?
- 6. Are there any side effects?
- 7. Product details

I. Why am I being given Flucloxacillin Kabi?

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

Flucloxacillin Kabi, like other antibiotics, will not work against infections caused by viruses such as colds or the flu.

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.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

2. What should I know before I am given Flucloxacillin Kabi?

Warnings

Do not use Flucloxacillin Kabi if:

1. You have had an allergic reaction to flucloxacillin or other penicillins. Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling.

2. You have had an allergic reaction to cephalosporin antibiotics.

You may have an increased chance of being allergic to Flucloxacillin Kabi if you are allergic to cephalosporins.

3. You have a previous history of inflammation of the liver or yellow skin caused by flucloxacillin.

4. The packaging is torn or shows signs of tampering.

5. The expiry date (exp) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be given Flucloxacillin Kabi, talk to your doctor.

WARNING

Flucloxacillin can cause jaundice (yellowing of skin and/or eyes) and severe liver disease which may be last for a long time. This reaction is more frequent in older patients (particularly those over 55 years of age) and those who take the drug for more than 14 days.

Before you are given it

Tell your doctor or pharmacist if:

1. You have any type of allergic reaction to penicillin, amoxicillin or cephalosporin antibiotics.

You may have an increased chance of being allergic to Flucloxacillin Kabi if you are allergic to cephalosporins.

2. You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes. This may include medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

3. You have, or have ever had, any other medical conditions including:

- asthma, hayfever or hives
- liver problems
- kidney problems
- glandular fever (infectious
- mononucleosis)

4. Your skin and/or eyes have turned yellow (jaundice) while, or soon after, receiving any antibiotics.

If you have not told your doctor or pharmacist any of the above, tell them before you are given Flucloxacillin Kabi During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or breastfeeding, intend to become pregnant or breastfeed. Your doctor will discuss the possible risks and benefits of using Flucloxacillin Kabi during pregnancy.

Check with your doctor if you are breast-feeding or plan to breast-feed. Your doctor will discuss the possible risks and benefits of using Flucloxacillin Kabi while breast-feeding.

3. What if I am taking other medicines?

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

Some medicines may be affected by Flucloxacillin Kabi, or they may affect how well it works.

These include:

- probenecid, a medicine used to treat gout
- paracetamol

• aminoglycosides; a group of antibiotic medicines used to treat some infections.

Some antibiotics may decrease the effectiveness of some birth control pills. Talk to your doctor about the need for an additional method of contraception whilst receiving Flucloxacillin Kabi.

You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor will advise you.

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

4. How am I given Flucloxacillin Kabi

Flucloxacillin Kabi is available in two strengths – 500mg and 1000mg.

Flucloxacillin Kabi 500mg and 1000mg injection is diluted and then given:

- as an injection into a vein
- as a deep injection into a large muscle
- in fluids given into a vein
- into the space around the lungs
- within a joint

Flucloxacillin Kabi must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive Flucloxacillin Kabi.

This depends on your infection and other factors, such as your weight. For most infections, Flucloxacillin Kabi is usually given in divided doses throughout the day.

If you receive too much (overdose)

As Flucloxacillin Kabi is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor immediately.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) 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 Flucloxacillin Kabi. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in the <u>6. Are there any side effects?</u> section but are usually of a more severe nature.

5. What should I know after receiving Flucloxacillin Kabi?

Things you must do

Call your doctor straight away if:

- the symptoms of your infection do not improve within a few days, or if they become worse.
- you develop itching with swelling or skin rash or difficulty breathing while you are receiving Flucloxacillin Kabi.
- you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Flucloxacillin has been stopped. 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.**
- you get a sore white mouth or tongue while being treated with or soon after stopping Flucloxacillin Kabi.
- you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of Flucloxacillin Kabi allows fungi to grow and the above symptoms to occur. Flucloxacillin Kabi does not work against fungi.

If you become pregnant while you are receiving Flucloxacillin Kabi, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Flucloxacillin Kabi.

If you have to have any blood or urine tests, tell your doctor you are being given Flucloxacillin Kabi.

Flucloxacillin Kabi may affect the results of some blood or urine tests.

Tell all the doctors dentists and pharmacists who are treating you that you are being given Flucloxacillin Kabi.

Things you must do

Do not take any diarrhoea medicine without first checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how flucloxacillin affects you.

This medicine does not generally cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, flucloxacillin may cause dizziness in some people.

If you experience dizziness, do not drive.

If you drink alcohol, dizziness may be worse.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Flucloxacillin Kabi should be stored in the pharmacy or in the ward.

The powder for injection is kept in a cool dry place where the temperature stays below 25°C.

6. Are there any side effects?

Check with your doctor as soon as possible if you have any problems while being treated with Flucloxacillin Kabi, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Flucloxacillin Kabi can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

If you are over 65 years of age you may have an increased chance of getting side effects.

You may not experience any of them.

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

Less serious side effects

Less serious side effects	What to do
 oral thrush - white, furry, sore tongue and mouth 	Speak to your doctor if you have any of
 vaginal thrush - sore and itchy vagina and/or discharge 	these less serious side effects and
nausea, stomach upsets	they worry you.
 mild diarrhoea or constipation 	
dizziness or headaches	
 pain or an uncomfortable feeling in the stomach or belching after eating. 	

Serious side effects

Serious side effects	What to do
 signs of an allergic reaction, such as shortness of breath wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body red and/or itchy skin, rash or hive on the skin difficulty breathing 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
• swelling	
 yellowing of the skin and/or eyes (these may be symptoms of a type of liver disease called jaundice) 	
• nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine (these may be symptoms of a type of liver disease called hepatitis)	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Flucloxacillin Kabi contains

Active ingredient (main ingredient)	Flucloxacillin sodium monohydrate
Other ingredients (inactive ingredients)	Flucloxacillin Kabi does not contain any other ingredient.
Potential allergens	Flucloxacillin Kabi does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Flucloxacillin Kabi looks like

Flucloxacillin Kabi is white or almost white crystalline powder for injection contained in a vial. (Aust R 340130 and 340131).

Who distributes Flucloxacillin Kabi

Flucloxacillin Kabi is supplied in Australia by: Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia Tel: (02) 9391 5555 This leaflet was prepared in Oct 2023.