DICLOXACILLIN VIATRIS

Consumer Medicine Information (CMI) summary

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

1. Why am I taking DICLOXACILLIN VIATRIS?

DICLOXACILLIN VIATRIS contains the active ingredient dicloxacillin. DICLOXACILLIN VIATRIS is used to treat infections in different parts of the body caused by bacteria.

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

2. What should I know before I take DICLOXACILLIN VIATRIS?

Do not take if you have ever had an allergic reaction to dicloxacillin 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 <u>2. What should I know</u> <u>before I take DICLOXACILLIN VIATRIS?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DICLOXACILLIN VIATRIS and affect how it works.

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

4. How do I take DICLOXACILLIN VIATRIS?

- Your doctor will tell you how much DICLOXACILLIN VIATRIS you need to take each day.
- For most infections, the usual dose for adults and children over 12 years is 250 mg to 500 mg every 6 hours.

More instructions can be found in Section <u>4. How do I</u> take DICLOXACILLIN VIATRIS? in the full CMI.

5. What should I know while taking DICLOXACILLIN VIATRIS?

Things you should do	 Remind any doctor,
	dentist or pharmacist you visit that you are taking DICLOXACILLIN VIATRIS.
	 If your symptoms of infection do not improve within a few days, or they become worse, tell your doctor.
	 If you get severe diarrhoea, even if it occurs several weeks after stopping DICLOXACILLIN VIATRIS, tell your doctor or pharmacist immediately.
	 If you develop a yellow discolouration of the skin or eyes, or your stools become pale and you feel unwell, tell your doctor immediately.
Things you should not do	 Do not stop taking DICLOXACILLIN VIATRIS even if you feel

	 better after a few days, unless advised to by your doctor. Do not use DICLOXACILLIN VIATRIS to treat any other conditions unless advised to by your doctor. Do not give DICLOXACILLIN VIATRIS to anyone else, even if their symptoms seem similar to yours.
Looking after your medicine	 Keep your capsules in the bottle until it is time to take them. Keep DICLOXACILLIN VIATRIS in a cool dry place below 25°C. Keep your medicine where children cannot reach it.

For more information, see Section <u>5. What should I know</u> while taking DICLOXACILLIN VIATRIS? in the full CMI.

6. Are there any side effects?

Less serious side effects include nausea, vomiting, stomach upset, wind, loose stools, oral thrush or vaginal thrush.

Serious side effects include watery or severe diarrhoea which may also be bloody, blood in urine, excess protein in urine, severe stomach cramps, yellowing of the skin or eyes (jaundice), pale stools, kidney problems, any type of skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or difficulty breathing.

This is not a complete list of side effects.

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

DICLOXACILLIN VIATRIS

Active ingredient: dicloxacillin sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about taking DICLOXACILLIN VIATRIS. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking DICLOXACILLIN VIATRIS.

Where to find information in this leaflet:

1. Why am I taking DICLOXACILLIN VIATRIS?

2. What should I know before I take DICLOXACILLIN VIATRIS?

- 3. What if I am taking other medicines?
- 4. How do I take DICLOXACILLIN VIATRIS?

5. What should I know while taking DICLOXACILLIN VIATRIS?

6. Are there any side effects?

7. Product details

1. Why am I taking DICLOXACILLIN VIATRIS?

DICLOXACILLIN VIATRIS contains the active ingredient dicloxacillin sodium. DICLOXACILLIN VIATRIS is antibiotic that belongs to a group of medicines called penicillins. These medicines work by killing the bacteria that are causing your infection.

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

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

Ask your doctor if you have any questions about why DICLOXACILLIN VIATRIS has been prescribed for you. Your doctor may have prescribed DICLOXACILLIN VIATRIS for another purpose.

There is no evidence that DICLOXACILLIN VIATRIS is addictive.

2. What should I know before I take DICLOXACILLIN VIATRIS?

Warnings

Do not take DICLOXACILLIN VIATRIS if:

 you are allergic to medicines containing dicloxacillin or any other penicillin e.g. amoxicillin, cephalosporin antibiotics or 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, mouth, throat or other parts of the body

- shortness of breath, wheezing or troubled breathing. Always check the ingredients to make sure you can take this medicine.
- the expiry date printed on the bottle has passed.
 If you take the medicine after the expiry date, it may not work as well.
- the packaging shows signs of tampering or the capsules do not look quite right.

Check with your doctor if you:

 have had any type of allergic reaction to other penicillins e.g. amoxicillin, or cephalosporin antibiotics.

You may have an increased chance of being allergic to DICLOXACILLIN VIATRIS if you are allergic to cephalosporins.

- are allergic to any other medicines, foods, dyes or preservatives.
- have, or have had, any other health problems or medical conditions, especially the following:
 - stomach problems such as feeling sick (nausea), vomiting or indigestion
 - problems with food absorption
 - liver problems
 - kidney problems
 - cystic fibrosis.

Your doctor may want to take special care or adjust your dose if you have any of these conditions.

Check with your doctor or pharmacist if you are not sure about any of the above.

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

Tell your doctor if you are pregnant or plan to become pregnant.

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

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

Like many other medicines, DICLOXACILLIN VIATRIS can pass into breast milk. Your doctor will discuss the risks and benefits of taking DICLOXACILLIN VIATRIS when breastfeeding.

Use in newborn infants

DICLOXACILLIN VIATRIS is not recommended for use in newborn infants as its safety and effectiveness has not been established in this age group.

Use in patients over 55 years old

Some side effects occur more frequently in this age group. Your doctor will discuss the risks and benefits of taking DICLOXACILLIN VIATRIS with you.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking DICLOXACILLIN VIATRIS.

3. What if I am taking other medicines?

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

Some medicines may interfere with DICLOXACILLIN VIATRIS and affect how it works. These include:

- probenecid, a medicine used to treat gout
- warfarin, a medicine used to prevent blood clots
- phenytoin, a medicine used to treat epilepsy.

Your doctor can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking DICLOXACILLIN VIATRIS.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DICLOXACILLIN VIATRIS.

4. How do I take DICLOXACILLIN VIATRIS?

Follow all directions given to you by your doctor and 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.

How much to take

- The dose varies from person to person.
- Your doctor will tell you how much DICLOXACILLIN VIATRIS you need to take each day.
- For most in infections, the usual dose for adults and children over 12 years is 250 mg to 500 mg every 6 hours.

How to take DICLOXACILLIN VIATRIS

- Swallow the capsules whole with a glass of water.
- Take DICLOXACILLIN VIATRIS on an empty stomach, 1 to 2 hours before food.

Taking the capsules on an empty stomach means that more of the medicine is absorbed into your body.

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 DICLOXACILLIN VIATRIS for

• Keep taking DICLOXACILLIN VIATRIS until you finish your bottle, or for as long as your doctor recommends.

If you forget to take DICLOXACILLIN VIATRIS

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 capsules as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you miss more than one dose, or are not sure what to do, ask your doctor or pharmacist.

If you take too much DICLOXACILLIN VIATRIS

If you think that you or anyone else has taken too much DICLOXACILLIN VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or

 go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking DICLOXACILLIN VIATRIS?

Things you should do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking DICLOXACILLIN VIATRIS.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking DICLOXACILLIN VIATRIS.
- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- If you get a sore, white mouth or tongue while taking or soon after stopping DICLOXACILLIN VIATRIS, 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 DICLOXACILLIN VIATRIS allows fungi to grow and these symptoms to occur. DICLOXACILLIN VIATRIS does not work against fungi.

• If you are taking more than one or two courses of DICLOXACILLIN VIATRIS, you may need to have tests to check your liver, kidneys or blood.

Always follow your doctor's instructions and have the tests performed as directed.

Call your doctor straight away if you:

 get severe diarrhoea, even if it occurs several weeks after stopping DICLOXACILLIN VIATRIS.

Diarrhoea may mean you have a serious condition affecting your bowel. You may need urgent medical care.

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

 develop a yellow discolouration of the skin or eyes, your stools become pale and you feel unwell.

These symptoms may mean that you have a serious problem with your liver. You may need urgent medical care.

Things you should not do

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

If you stop taking DICLOXACILLIN VIATRIS too soon, your infection may not clear completely and your symptoms may return.

- Do not use DICLOXACILLIN VIATRIS to treat any other conditions unless advised to by your doctor.
- Do not give DICLOXACILLIN VIATRIS to anyone else, even if their symptoms seem similar to yours.

Looking after your medicine

- Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the bottle they may not keep well.
- Store below 25°C.

Follow the instructions on the bottle 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.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop taking DICLOXACILLIN VIATRIS, or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DICLOXACILLIN VIATRIS. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects	What to do
 nausea (feeling sick), vomiting, stomach upset, wind, loose stools oral thrush (white, furry sore tongue and mouth) vaginal thrush (sore and itchy vagina, vaginal discharge) 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects

Serious side effects

Serious side effects	What to do
 watery and severe diarrhoea, which may also be bloody blood in the urine 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
 excess protein in the urine severe stomach cramps yellowing of the skin or eyes (jaundice), pale stools kidney problems 	notice any of these serious side effects.
 any type of skin rash, itching or hives swelling of the face, lips, mouth, throat or other parts of the body shortness of breath, wheezing or difficulty breathing 	Stop taking DICLOXACILLIN VIATRIS and call your doctor straight away, or go to the Emergency Department at your nearest hospital if you notice any of these side effects.

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

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

Some people may have side effects that are not listed here.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell while you are taking, or soon after you have finished taking DICLOXACILLIN VIATRIS, even if it is not on the list.

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 DICLOXACILLIN VIATRIS contains

Active ingredient (main ingredient)	dicloxacillin sodium
Other ingredients (inactive ingredients)	 colloidal anhydrous silica magnesium stearate gelatin

	 titanium dioxide purified water TekPrint SW-9008 Black Ink (ID 2328)
Potential allergens	DICLOXACILLIN VIATRIS 250 mg tablets contain sulfites and 21.2 mg of sodium per dose.
	DICLOXACILLIN VIATRIS 500 mg tablets contain sulfites 42.5 mg of sodium per dose.

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

What DICLOXACILLIN VIATRIS looks like

DICLOXACILLIN VIATRIS 250 mg is a size 2 capsule with white opaque body and cap, printed 'DX' on the cap and '250' on the body in black (AUST R 289105).

DICLOXACILLIN VIATRIS 500 mg is a size 0 capsule with white opaque body and cap, printed 'DX' on the cap and '500' on the body in black (AUST R 289107).

Each bottle contains 24 capsules.

Who distributes DICLOXACILLIN VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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