NEXIUM® Hp7®

Consumer Medicine Information (CMI) summary

The full CMI 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 using NEXIUM Hp7?

NEXIUM Hp7 is a combination pack which contains three different medicines with active ingredients esomeprazole, amoxicillin trihydrate and clarithromycin. When taken together in the right doses, they will kill the bacteria in your stomach called Helicobacter pylori and let your peptic ulcer heal.

For more information, see Section 1. Why am I using NEXIUM Hp7? in the full CMI.

2. What should I know before I use NEXIUM Hp7?

Do not use if you have ever had an allergic reaction to NEXIUM Hp7 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 use NEXIUM Hp7? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEXIUM Hp7 and affect how it works.

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

4. How do I use NEXIUM Hp7?

- NEXIUM Hp7 is taken in the following dose: NEXIUM: Take one 20 mg tablet in the morning and one 20 mg tablet at night; AMOXIL: Take two 500 mg capsules in the morning and two 500 mg capsules at night; KLACID: Take one 500 mg tablet in the morning and one 500 mg tablet at night.
- It is very important that you take NEXIUM Hp7 exactly in the dose above or follow all directions given to you by your doctor and pharmacist carefully.

More instructions can be found in Section 4. How do I use NEXIUM Hp7? in the full CMI.

5. What should I know while using NEXIUM Hp7?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using NEXIUM Hp7. • Tell your doctor if your symptoms return.
Things you should not do	• Do not stop using this medicine, or change any of the doses, unless your doctor tells you to. • Do not give NEXIUM Hp7 to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how NEXIUM Hp7 affects you.
Looking after your medicine	• Keep the three medicines in NEXIUM Hp7 in their separate blisters until it is time to take them. • Keep them in a cool dry place where the

	temperature stays below 25°C.

For more information, see Section 5. What should I know while using NEXIUM Hp7? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include diarrhoea, nausea or vomiting, headache, dizziness, constipation, loss of appetite, stomach pain (e.g. cramps), wind, dryness of the mouth or other body cavities, soreness of mouth, throat or tongue, "pins and needles", metallic taste or other change in taste or smell, chills, fatigue and excessive burping. 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.

NEXIUM® Hp7®

Active ingredients: *esomeprazole, amoxicillin trihydrate and clarithromycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NEXIUM Hp7. **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 NEXIUM Hp7.**

Where to find information in this leaflet:

1. Why am I using NEXIUM Hp7?
2. What should I know before I use NEXIUM Hp7?
3. What if I am taking other medicines?
4. How do I use NEXIUM Hp7?
5. What should I know while using NEXIUM Hp7?
6. Are there any side effects?
7. Product details

1. Why am I using NEXIUM Hp7?

NEXIUM Hp7 contains active ingredients esomeprazole, amoxicillin trihydrate, and clarithromycin. It is a combination pack which contains three different medicines. When taken together in the

right doses, they will kill the bacteria in your stomach called *Helicobacter pylori* and let your peptic ulcer heal.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach. Most people who have a peptic ulcer also have a bacterium called *Helicobacter pylori* in their stomach. If the bacteria are killed it is unlikely that your ulcer will come back.

NEXIUM is the brand name of esomeprazole (E), and it is given with amoxicillin (A), brand name AMOXIL and clarithromycin (C), brand name KLACID. AMOXIL and KLACID are both types of antibiotics.

NEXIUM is a type of medicine called a proton-pump inhibitor. NEXIUM works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way. Amoxicillin trihydrate and clarithromycin are both antibiotics that help kill *Helicobacter pylori*. NEXIUM also helps kill the bacteria. When all three are taken together they are more effective than taken one or two at a time. It is possible that the antibiotics may not always kill *Helicobacter pylori*.

2. What should I know before I use NEXIUM Hp7?

Warnings

Do not use NEXIUM Hp7 if:

- you are allergic to esomeprazole, amoxicillin trihydrate, and clarithromycin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to any medicines containing proton-pump inhibitors, penicillins, cephalosporins or macrolide antibiotics.

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 NEXIUM Hp7 if you are taking the following medicines:

- ergotamine
- dihydroergotamine
- cisapride

- pimozide
- astemizole
- terfenadine
- cilostazol
- atazanavir
- colchicine
- simvastatin
- lovastatin
- ticagrelor
- ranolazine
- oral midazolam
- domperidone
- lomitapide

Some medicines may interfere with NEXIUM Hp7 and affect how it works.

Please check with your doctor or pharmacist if you are taking any of these medicines. These medicines will be affected by the medicines in NEXIUM Hp7 and it is more likely you will get side effects.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- problems with your blood
- problems with your liver or kidneys
- any heart conditions, such as QT prolongation or ventricular cardiac arrhythmia
- you have glandular fever

- myasthenia gravis, a condition in which the muscles become weak and tire easily
- been diagnosed with osteoporosis
- low potassium, low magnesium or any other electrolyte imbalances
- ever had a skin reaction after treatment with a medicine similar to NEXIUM Hp7 that reduces stomach acid

There is no evidence that NEXIUM Hp7 is addictive.

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 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known if it is safe for you to take NEXIUM Hp7 if you are pregnant. The medicines in NEXIUM Hp7 may affect the developing baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your baby can take in all the medicines in NEXIUM Hp7 from breast milk if you are breast-feeding. NEXIUM Hp7 is not recommended when breast-feeding.

Your doctor can discuss with you the risks and benefits of using NEXIUM Hp7 if you are pregnant or breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking NEXIUM Hp7.

Children

NEXIUM Hp7 is not recommended for use in children. There is no information about the use of NEXIUM Hp7 in children.

Other medical conditions

- Do not take NEXIUM Hp7 if you have a history of heart conditions such as QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes.
- Do not take NEXIUM Hp7 if you have low magnesium or potassium levels.
- Do not take NEXIUM Hp7 if you have both liver and kidney problems.

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.

Do not take NEXIUM Hp7 if you are taking the following medicines:

- ergotamine or dihydroergotamine - medicines used to treat migraine headaches
- astemizole or terfenadine - medicines used to treat hay fever and allergies

- atazanavir - a medicine used to treat Human Immunodeficiency Virus (HIV)
- cilostazol - a medicine used to treat intermittent claudication
- colchicine - a medicine used to treat gout
- lovastatin or simvastatin (statins) - medicines used to treat high cholesterol
- ticagrelor - a medicine used to treat blood clots
- oral midazolam - a medicine used for surgical sedation
- domperidone - a medicine used for nausea
- ranolazine - a medicine used to treat angina (chest pain)
- cisapride - a medicine used to treat gastric reflux
- pimozide - a medicine used to treat psychiatric conditions, such as schizophrenia
- lomitapide - a medicine used to treat high cholesterol

Some medicines may affect NEXIUM Hp7 or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

These include:

- diazepam, triazolam or alprazolam - medicines used as sedatives or to treat anxiety
- ketoconazole, itraconazole, voriconazole or fluconazole - medicines used to treat fungal infections
- warfarin, apixaban, rivaroxaban, dabigatran and clopidogrel - medicines used to prevent blood clots

- allopurinol or probenecid - medicines used to treat gout
- methotrexate, a medicine used to treat arthritis and some types of cancers
- phenytoin, sodium valproate or carbamazepine - medicines used to treat seizures
- atorvastatin or rosuvastatin (statins) - medicines used to treat high cholesterol
- theophylline - a medicine used to treat asthma
- zidovudine, saquinavir, efavirenz, etravirine, nevirapine, nelfinavir or ritonavir - medicines used to treat HIV
- insulin, repaglinide, nateglinide, pioglitazone or rosiglitazone - medicines used to treat diabetes
- digoxin, quinidine or disopyramide - medicines used to treat heart conditions
- citalopram, fluoxetine, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- rifabutin, rifapentine, rifampicin or erythromycin - medicines used to treat bacterial infections
- sildenafil, tadalafil or vardenafil - medicines used to treat impotence
- tolterodine - a medicine used to treat incontinence
- verapamil, amlodipine or diltiazem - medicines used to treat high blood pressure and some heart conditions
- methylprednisolone – a corticosteroid
- vinblastine - a medicine used to treat cancer

- oral contraceptives or birth control pills. Talk to your doctor about the need for an additional method of contraception while on NEXIUM Hp7
- tacrolimus or ciclosporin - medicines used to prevent organ transplant rejection or to treat certain problems with the immune system
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- phenobarbitone - a medicine used to treat epilepsy
- tetracycline and aminoglycoside antibiotics - medicines used to treat certain infections
- atypical antipsychotics - medicines used to treat psychiatric conditions, such as schizophrenia and bipolar disorder (e.g. quetiapine)
- ibrutinib - a medicine used to treat cancer

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEXIUM Hp7.

4. How do I use NEXIUM Hp7?

How much to take

There are three different medicines in NEXIUM Hp7. It is very important that you take NEXIUM Hp7 exactly as follows:

NEXIUM (esomeprazole) = E

Take one 20 mg tablet in the morning and one 20 mg tablet at night.

AMOXIL (amoxicillin trihydrate) = A

Take two 500 mg capsules in the morning and two 500 mg capsules at night.

KLACID (clarithromycin) = C

Take one 500 mg tablet in the morning and one 500 mg tablet at night.

Morning

1 E, 2 A, 1 C

Night

- 1 E, 2 A, 1 C

Follow the instructions provided when NEXIUM Hp7 was prescribed, including the number of days it should be taken. Continue taking the capsules and tablets until you finish the course or until your doctor tells you to stop.

If you do not complete the full course prescribed by your doctor, the Helicobacter pylori may not clear completely and your symptoms may return.

Tell your doctor if your symptoms return.

It is possible that the antibiotics may not kill *Helicobacter pylori*. You may need treatment with more antibiotics.

When to take NEXIUM Hp7

- Take NEXIUM Hp7 at about the same time each day.
- Take NEXIUM Hp7 during or after meals.

- Keeping a regular time for taking NEXIUM Hp7 will help to remind you to take it.

How to take NEXIUM Hp7

Swallow the NEXIUM tablets whole with a glass of water. For patients with swallowing difficulties, the tablet can be placed in half a glass of non-carbonated water (mineral water is not suitable). The tablet may be gently mixed and care should be taken not to crush the tablet. Rinse the glass with half a glass of fluid and drink.

NEXIUM tablets may also be administered, dispersed in non-carbonated water, through a gastric tube.

Do not crush or chew the tablets as they will not work properly.

If you forget to use NEXIUM Hp7

If you miss any of the medicines in NEXIUM Hp7 at the usual time, take it as soon as you remember, as long as it is more than four hours before the next dose of that medicine is due.

If it has been more than 4 hours after you usually take your dose, skip that dose. Take the next dose at your usual time.

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

If you use too much NEXIUM Hp7

If you think that you have used too much NEXIUM Hp7, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.

If you take too much NEXIUM Hp7 you may vomit and have severe stomach problems.

5. What should I know while using NEXIUM Hp7?

Things you should do

Take NEXIUM Hp7 exactly as your doctor has prescribed.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking NEXIUM Hp7.

If you become pregnant while you are taking NEXIUM Hp7, tell your doctor.

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after NEXIUM Hp7 has been stopped.

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

If you get a sore, white mouth or tongue while taking, or soon after stopping NEXIUM Hp7, 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 NEXIUM Hp7 allows fungi to grow and the above symptoms to occur. NEXIUM Hp7 does not work against fungal infections.

Remind any doctor, dentist or pharmacist you visit that you are using NEXIUM Hp7.

If you need to have any medical tests while you are taking NEXIUM Hp7, tell your doctor. It may affect the results of some tests.

Drink plenty of water or fluids while taking NEXIUM Hp7.

Things you should not do

- Do not take NEXIUM Hp7 to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- Do not stop taking NEXIUM Hp7, or change any of the doses, unless you have discussed it with your doctor.

You need to take all the capsules and tablets in the pack for it to work properly. If you stop taking it, your ulcer may come back and be harder to treat next time.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NEXIUM Hp7 affects you.

NEXIUM Hp7 may cause dizziness in some people. Make sure you know how you react to NEXIUM Hp7 before you do anything that may be dangerous if you are dizzy.

Looking after your medicine

- Keep the three medicines in NEXIUM Hp7 in their separate blisters until it is time to take them.
- Keep it in a cool dry place where the temperature stays below 25°C.

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.

Heat and dampness can destroy some medicines.

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 you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• diarrhoea, nausea or vomiting • headache • dizziness • constipation • loss of appetite • stomach pain (e.g. cramps)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• wind • dryness of the mouth or other body cavities • soreness of mouth, throat or tongue • "pins and needles" • metallic taste or other change in taste or smell • chills • fatigue • excessive burping	

Serious side effects

Serious side effects	What to do
• muscle pain or weakness • increase in breast size (males) • fever • changes in sleep patterns • mood changes, hallucinations, confusion or depression • change in sexual function	**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.**

Serious side effects	What to do
• blurred vision, hearing disturbances • hair loss • bleeding or bruising more easily than normal • signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers • skin rash • blood in urine • tremor • convulsions or fits • overgrowth of yeast infections (thrush) • fainting • yellowing of the eyes or skin • muscle twitching or jerking movements • irregular (fast or slow) heartbeat • loss of consciousness or awareness	
• shortness of breath, wheezing or difficulty breathing	**Stop taking NEXIUM Hp7 and tell your**

Serious side effects	What to do
• swelling of the face, lips, tongue or other parts of the body • chest pain • severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin • severe upper stomach pain, with nausea and vomiting • signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite • skin reaction, especially in sun-exposed areas, with joint pain • headache, increased sensitivity to light, neck stiffness, unsteadiness, fits • severe stomach or abdominal cramps, watery and severe diarrhoea, which may also be bloody (this may	**doctor immediately or go straight to the Emergency Department at your nearest hospital if any of these serious side effects happen.** **Do not take any medicine to stop the diarrhoea unless advised by your doctor.**

Serious side effects	What to do
occur several weeks after you stop taking NEXIUM Hp7)	

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.

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

You may not experience any of them.

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 www.tga.gov.au/reporting-problems. 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 NEXIUM Hp7 contains

Active ingredient **(main ingredients)**	• NEXIUM: esomeprazole • AMOXIL: amoxicillin trihydrate • KLACID: clarithromycin
Other ingredients **(inactive ingredients)**	**NEXIUM:** • glyceryl monostearate • hyprolose • hypromellose • magnesium stearate • methacrylic acid copolymer • microcrystalline cellulose • synthetic paraffin • macrogol 6000 • polysorbate 80 • crospovidone • sodium stearylfumarate • purified talc • triethyl citrate • sugar spheres (maize starch and sucrose)

	The tablets are coloured with titanium dioxide, iron oxide red and iron oxide yellow. **AMOXIL:** • magnesium stearate • purified talc • gelatin The hard gelatin capsule is coloured with titanium dioxide, iron oxide yellow, erythrosine, indigo carmine and Tek Product-Tek Print SW-0012 White Ink. **KLACID:** • croscarmellose sodium • microcrystalline cellulose • povidone • silicon dioxide • hyprolose • hypromellose • purified talc • sorbitan mono-oleate • stearic acid • magnesium stearate

	• propylene glycol • sorbic acid • vanillin • titanium dioxide • quinoline yellow
Potential allergens	• **NEXIUM:** • sugars • sorbates **KLACID:** • sorbates

NEXIUM Hp7 does not contain gluten.

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

What NEXIUM Hp7 looks like

NEXIUM Hp7 is a combination pack containing three different medicines (AUST R 281690).

- NEXIUM tablets 20 mg are light pink, oblong shaped, marked with '20 mg' on one side and 'A/EH' on the other side. NEXIUM is provided in a blister packs of 14 tablets. (Aust R 74133)
- AMOXIL capsules 500 mg are red and yellow capsules, marked with 'AM500'. AMOXIL is provided in blister packs of 28 capsules. (Aust R 273936)
- KLACID tablets 500 mg are pale yellow, oval, film coated tablets. KLACID is provided in blister packs of 14 tablets. (Aust R 52473)

Who distributes NEXIUM Hp7

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

This leaflet was prepared in April 2024.

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