

PACKAGE LEAFLET

1 Name of Product

ZOLCER KIT

2 Description of Product

A. Omeprazole Delayed-Release Capsules USP 20 mg

A dark blue/light blue, size “2”, unprinted, hard gelatin capsule, containing white to off white, circular, granules.

B. Tinidazole Tablets 500 mg: A Yellow coloured, circular, biconvex, film- coated, tablet.

C. Clarithromycin Tablets USP 250 mg: An orange coloured, circular, biconvex, film coated tablet having lip type break line on one side of the tablet.

Dosage form: Oral Tablet and Capsule.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **ZOLCER KIT** are and what they are used for
2. Before you take **ZOLCER KIT**
3. How to take **ZOLCER KIT**
4. Possible side effects
5. How to store **ZOLCER KIT**
6. Further information

1. WHAT ARE ZOLCER KIT TABLETS AND WHAT THEY ARE USED FOR

ZOLCER KIT belong to a group of drugs

A) **OMEPRAZOLE** Category: Proton pump inhibitor

B) **TINIDAZOLE** Category: an antiprotozoal.

C) **CLARITHROMYCIN** Category: macrolide antibiotic

You take **ZOLCER KIT** in that Omeprazole Delayed- Release Capsules USP 20 mg the treatment of Duodenal and gastric ulcers, reflux or ulcerative oesophagitis. Zollinger-Ellison syndrome. Tinidazole Tablets 500 mg for treatment Eradication of

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Helicobacter pylori associated with duodenal ulcers, in the presence of antibiotic and acid suppressant therapy. Clarithromycin Tablets USP 250 mg for the treatment of the following acute and chronic bacterial infections, when caused by susceptible bacteria.

2. BEFORE YOU TAKE ZOLCER KIT tablets

Do not take **ZOLCER KIT** if you:

- are allergic (hypersensitive) to **ZOLCER KIT** or any of the other ingredients of **ZOLCER KIT**
- are pregnant, breast-feeding or planning to become pregnant
- have a blood disorder or a history of blood disorders.
- have central nervous system (CNS) disease, including epilepsy.
- have an irregular heart rhythm.
- If you are taking a medicine containing nelfinavir (used for HIV infection)
- are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.

Tell your doctor if you:

If you take OMEPRAZOLE capsule on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like OMEPRAZOLE capsule, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

- You should always tell your doctor if you are taking or have recently taken any other medicines including those obtained without a prescription

-You should tell your doctor if you are currently taking blood thinners such as prevent blood clots as your doctor may wish to monitor you more closely.

- if you have any liver or kidney problems, fungal infections (e.g. thrush)

If any of these apply to you, consult your doctor before taking Clarithromycin Tablets USP 250 mg.

Taking other medicines

Always tell your doctor if you are taking other medicines including herbal remedies and non-prescription medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungus)

Digoxin (used to treat heart problems)

Diazepam (used to treat anxiety, relax muscles or in epilepsy)

Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will when you start or stop taking OMEPRAZOLE capsule.

Medicines that are used to thin your blood, such as warfarin or other vitamin doctor may need to monitor you when you start or stop taking OMEPRAZOLE capsule
Rifampicin (used to treat tuberculosis)

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You should tell your doctor if you are currently taking blood thinners such as warfarin to prevent blood clots as your doctor may wish to monitor you more closely.

are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.

- are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm.
- are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).

Taking ZOLCER KIT with food and drink

You can take your capsules with food or on an empty stomach.

You should not drink wine, beer or spirits during treatment and for 3 days after stopping treatment with Tinidazole Tablets 500 mg . The combination may cause flushing, stomach cramps, vomiting (being sick) and palpitations (pounding heart).

You should take Tinidazole Tablets 500 mg during or after a meal.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Before taking OMEPRAZOLE capsule , tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take OMEPRAZOLE capsule during this time. Your doctor will decide whether you can take OMEPRAZOLE capsule if you are breast-feeding.

You should not take Tinidazole Tablets 500 mg if you are in the first 13 weeks of pregnancy or are trying to become pregnant. Always ask your doctor or pharmacist for advice before taking Tinidazole Tablets 500 mg or any other medicine. You should not take Tinidazole Tablets 500 mg if you are breast feeding as small amounts can pass into your milk. If you stop breast-feeding during treatment you should not start again until at least 3 days after stopping Tinidazole Tablets 500 mg

If you are pregnant, think you may be pregnant, or if you are breast-feeding, consult your doctor before taking Clarithromycin Tablets USP 250 mg as the safety of Clarithromycin Tablets USP 250 mg in pregnancy and breast-feeding is not known.

Important information about some of the ingredients of ZOLCER KIT

OMEPRAZOLE capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ZOLCER KIT tablets

Dosage:

Always take OMEPRAZOLE capsule exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for.

This will depend on your condition and how old you are.

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The usual doses are given below.

Adults:

To treat symptoms of GORD such as heartburn and acid regurgitation:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The usual dose once the gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat ulcers in the upper part of the intestine (duodenal ulcer):

- The usual dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcer do not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat ulcers in the stomach (gastric ulcer):

- The usual dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To prevent the duodenal and stomach ulcers from coming back:

- The usual dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The usual dose is 20 mg once a day for 4–8 weeks.

To prevent duodenal and stomach ulcers if you are taking NSAIDs:

- The usual dose is 20 mg once a day.

To treat ulcers caused by Helicobacter pylori infection and to stop them coming back:

- The usual dose is 20 mg OMEPRAZOLE capsule twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger Ellison syndrome):

- The usual dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Children:

To treat symptoms of GORD such as heartburn and acid regurgitation:

- Children over 1 year of age and with a body weight of more than 10 kg may take OMEPRAZOLE capsule. The dose for children is based on the child's weight and the doctor will decide the correct dose.

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To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:

- Children aged over 4 years may take OMEPRAZOLE capsule. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Always take your tablets exactly as your doctor has told you and as written on the label on the pack. Check with your doctor or pharmacist if you are not sure.
Take Tinidazole Tablets 500 mg with a glass of water during or after a meal.
Swallow the tablets whole. It is best to take the medicine at the same time each day.

Children under 12 years

For bacterial infections, Tinidazole Tablets 500 mg is not recommended for use in children less than 12 years as it has not been tested in this age group.

For protozoal infections, Tinidazole Tablets 500 mg can be used in children and has not been shown to cause any different side effects or more problems than it does in adults.

The dose and length of treatment depends upon the infection being treated. If you are on dialysis, your doctor may prescribe a different dose.

The doses most commonly used for the different infections are shown in the table below:

For treating the infection associated with stomach ulcers:

The usual dose is 1 tablet (500mg) taken twice a day. Your doctor will probably prescribe two other medicines to be taken with Tinidazole Tablets 500 mg.

Treatment with the three medicines together will usually be for 1 week.

For treating most bacterial infections:

The usual dose is 4 tablets (2g) on the first day then 2 tablets (1g) once a day or 1 tablet (500mg) twice a day.

The usual length of treatment is 5 to 6 days.

For treating bacterial vaginitis (a vaginal infection) and acute ulcerative gingivitis (a gum infection):

The usual dose is 4 tablets (2g) given as a single dose.

For vaginitis you may be given 4 tablets (2g) on two consecutive days.

For preventing bacterial infections after surgery:

Usually 4 tablets (2g) are given as a single dose about 12 hours before surgery.

For treating protozoal infections:

For treating intestinal amoebiasis (a stomach infection)

Adult The usual dose is 4 tablets (2g) once a day for 2 to 3 days.

Child The usual dose is 50 to 60mg/kg of body weight once a day for 3 days.

For treating amoebic involvement of the liver (a liver infection):

Adult The usual dose is 3 to 4 tablets (1.5 to 2g) once a day for 3 to 6 days.

Child The usual dose is 50 to 60mg/kg of body weight once a day for 5 days.

For treating giardiasis (an abdominal infection) and trichomoniasis (an infection of the sex organs in males and females):

Adult The usual dose is 4 tablets (2g) given as a single dose.

Child The usual dose is 50 to 75mg/kg of body weight given as a single dose.

Your doctor will calculate the dose required for a child and may repeat the dose once if the infection has not cleared up completely.

Do not give these tablets to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

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Always take Klaricid tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is; For chest infections, throat or sinus infections and skin and soft tissue infections: Usual dose of Klaricid tablets for adults and children over 12 years is 250 mg twice daily for 6 to 14 days, e.g. one 250 mg tablet in the morning and one in the early evening. Your doctor may increase the dose to 500 mg twice daily in severe infections.

Klaricid tablets should be swallowed with at least half a glass of water.

For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers: There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which Klaricid tablets are taken together with one or two other drugs.

These combinations include the following and are usually taken for 6 to 14 days:

- a) One Clarithromycin Tablets USP 250 mg taken twice a day together with amoxicillin, 1000 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- b) One Clarithromycin Tablets USP 250 mg taken twice a day together with metronidazole, 400 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- c) One Clarithromycin Tablets USP 250 mg taken twice a day together with amoxicillin, 1000 mg taken twice a day or metronidazole, 400 mg taken twice a day plus omeprazole, 40 mg a day.

The treatment combination that you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor for advice.

If you take more **ZOLCER KIT** than you should

If you take more OMEPRAZOLE capsule than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you take too much Tinidazole Tablets 500 mg tell your doctor or contact your nearest hospital casualty department immediately. Take any remaining tablets with you.

If you accidentally take more Clarithromycin Tablets USP 250 mg in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of Clarithromycin Tablets USP 250 mg is likely to cause vomiting and stomach pains.

If you forget to take your **ZOLCER KIT**

If you forget to take a dose of omeprazole capsule, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you forget to take Tinidazole Tablets 500 mg take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you forget to take a Klaricid tablet, take one as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

If you stop taking your **ZOLCER KIT**

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If you stop taking Tinidazole Tablets 500 mg too soon, the infection may return. Take Fasiqyn for the full time of treatment, even when you begin to feel better.

If you have any further questions about the use of this product, ask your doctor or pharmacist for advice.

Do not stop taking Clarithromycin Tablets USP 250 mg, even if you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ZOLCER KIT can have side effects, but not everybody gets them. If any of the following occur, stop taking the tablets and tell your doctor immediately: Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or swallowing (severe allergic reaction).

Reddening of the skin with blisters or peeling. There may also be severe blisters and the lips, eyes, mouth, nose and genitals. This could be ‘Stevens-Johnson syndrome’ epidermal necrolysis’.

Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Sudden wheeziness, difficulty in breathing, swelling of eyelids, tongue, rash or itching (especially affecting the whole body).

severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.

- a rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may have developed an allergic reaction.
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/ toxic epidermal necrolysis).
- Henoch-Schonlein purpura (a rash which appears as purple spots on the skin).

If any of the following occur, call your doctor as soon as possible:

Omeprazole capsule may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your

- dizziness or vertigo
- numbness, tingling, pain or weakness in hands or feet
- clumsiness or unsteadiness
- fits or seizures
- fever or chills and painful ulcers in the mouth or bottom (rectum)

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- sore or swollen mouth
 - redness of the face or neck.
- leaking of blood from blood vessels (haemorrhage)
- inflammation of the mouth or tongue
 - discolouration of the tongue or teeth
 - dry mouth
 - loss of taste or smell or inability to smell properly
 - joint pain
 - muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily) or rhabdomyolysis (a condition which causes the breakdown of muscle tissue), clarithromycin may worsen these symptoms
 - chest pain or changes in heart rhythm such as palpitations
 - a change in the levels of products made by the liver, inflammation of the liver or an inability of the liver to function properly (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin)
 - a change in the levels of products produced by the kidney, inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)
 - low blood sugar levels
 - a change in the levels of certain cells or products found in the blood.
- Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms.

5. HOW TO STORE ZOLCER KIT

- Keep out of the reach and sight of children.
- Store below 30°C. Protect from moisture.
- Do not use the medicine after the expiry date, which is stated on the carton after (EXP). The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What ZOLCER KIT contain

ZOLCER KIT contains:

A) Omeprazole Delayed-Release Capsules USP 20 mg: A dark blue / light blue, size “2”, unprinted, hard gelatin capsule, containing white to off white, circular, granules.

B) TINIDAZOLE TABLETS 500 mg: A Yellow coloured, circular, biconvex, film-coated, tablet.

C) CLARITHROMYCIN TABLETS USP 250 mg: An orange coloured, circular, biconvex, film coated tablet having lip type break line on one side and plain on other side.

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It contains are Non Pareil Seed 12#/16# IHS, Hard Gelatin Capsule Shells Size “2” Dark Blue/ Light Blue IHS, Maize Starch BP, Purified Water BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Gelatin BP, Purified Talc BP, Magnesium Stearate BP, Sodium starch glycolate (Type A), Colloidal Anhydrous Silica BP, Hypromellose BP, Isopropyl Alcohol BP, Dichloromethane BP, Diethyl phthalate BP, Titanium Dioxide BP, Colour Tartrazine Yellow Lake IHS, Microcrystalline Cellulose BP, Pregelatinised Starch BP, Croscarmellose Sodium BP, Calcium Stearate BP, Instacoat Universal IHS.

What ZOLCER KIT look like and contents of the pack

ZOLCER KIT contains:

A) Omeprazole Delayed-Release Capsules USP 20 mg: A dark blue / light blue, size “2”, unprinted, hard gelatin capsule, containing white to off white, circular, granules.

B) TINIDAZOLE TABLETS 500 mg: A Yellow coloured, circular, biconvex, film-coated, tablet.

C) CLARITHROMYCIN TABLETS USP 250 mg: An orange coloured, circular, biconvex, film coated tablet having lip type break line on one side and plain on other side.

Each kit contains: 2 capsules of omeprazole /2 tablets each of Tinidazole & Clarithromycin in Blister & 7 such kit in a Carton.

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7 Marketing Authorization Holder and Manufacturer:

Name and Address of Manufacturer

AUROCHEM LABORATORIES (INDIA) PVT. LTD.

At 58, Palghar Taluka,

Industrial Co.-op. Estate Ltd.

Palghar – 401 404,

Tel No. : 0252-552332, 0252-554720

District Thane,

Maharashtra, INDIA.

Name and Address of Marketing Authorization Holder

AUROCHEM LABORATORIES (INDIA) PVT. LTD.

334, Gundecha Industrial Complex, 3rd Floor, Akurli Road.

Kandivali (E), Mumbai - 400101,

India.

Tel: +(91)-(22)- 4250 9191

Fax: +(91)-(22)- 4250 9150

E-mail: info@eurochempharma.com

website: www.eurochemlaboratories.com

8 Date of Revision of PIL
