2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LANSOPRAZOLE

- If you have any further questions, ask your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you have been told by your doctor that you have an infection (antibiotics) or together with other medicines that reduce stomach acid. For those who take lansoprazole to make sure it contains important information for you.

3. HOW TO TAKE LANSOPRAZOLE

- Gastro-Oesophageal Reflux Disease (GORD). This is a condition called proton pump inhibitors.
- Healing ulcers in your stomach or duodenum (gut) lining. This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
- Your doctor has given you lansoprazole in addition to other medicines intended for the treatment of Helicobacter pylori infection (antibiotics) or together with anti-inflammatory medicines to treat pain or rheumatic disease. Please also read the package leaflet containing the other ingredients of these capsules (see Section 6: Contents of the pack and other information).

4. TAKING LANSOPRAZOLE WITH FOOD AND DRINK

- Lansoprazole works by lowering the amount of acid in your stomach.
- It can be used for:
  - Healing ulcers in your stomach or duodenum (gut). This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
  - Your doctor may arrange for you to have an endoscopic examination (where a very small camera is inserted down your oesophagus (food pipe) to look into your stomach). This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
  - Your doctor may then decide to give you one 15mg or 30mg capsule every day to stop the ulcer or your symptoms coming back.
- Do not take lansoprazole with food and drink. This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
- Your doctor will tell you when to stop taking lansoprazole.

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5. HOW TO STORE LANSOPRAZOLE

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you are not sure, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you are taking a medicine containing atazanavir (used to treat HIV) you may have to adjust your dose.
- You have osteoporosis or are taking a type of medicine called corticosteroids (which can increase the risk of osteoporosis). Taking a proton pump inhibitor, like lansoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the bones, wrist or spine.
- Your doctor will tell you when to stop taking lansoprazole.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LANSOPRAZOLE

- Do not take lansoprazole and tell your doctor if:
  - You are taking a medicine containing atazanavir (used to treat HIV).
  - You are taking lansoprazole together with 250-500 mg clarithromycin and 1000mg or 30 mg capsule every day to stop the ulcer or your symptoms coming back.
- Do not take lansoprazole with food and drink. This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
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2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LANSOPRAZOLE

- Do not take lansoprazole and tell your doctor if:
  - You are allergic (hypersensitive) to lansoprazole or any of the other ingredients in these capsules (see Section 6: Contents of the pack and other information).
  - You have liver problems. Your doctor may want to adjust your dose.
  - You have osteoporosis or are taking a type of medicine called corticosteroids (which can increase the risk of osteoporosis). Taking a proton pump inhibitor, like lansoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the bones, wrist or spine.
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  - You are allergic (hypersensitive) to lansoprazole or any of the other ingredients in these capsules (see Section 6: Contents of the pack and other information).
Gastro-oesophageal reflux disease (GOR):  
• One 30mg capsule every day for 4 weeks to heal your food pipe (oesophagus) and/or relieve symptoms  
• Your doctor may then decide you need one 15mg or 30mg capsule a day to stop your illness coming back

Indigestion caused by too much acid (acid-related dyspepsia)
• One 15mg or 30mg capsule every day for 2 to 4 weeks  
• Take your doctor once you have completed this course or if your symptoms are not getting better  

Zollinger-Ellison syndrome
• Your doctor will then decide the dose which is best for you and talk to you about how you respond to treatment with lansoprazole

Patients with liver problems
• If you have severe liver problems your doctor may keep your dose to one capsule a day.
• Children  
  • Do not give lansoprazole to children.
• If you take more lansoprazole than you should  
  • Tell your doctor or nearest hospital straightaway if:

Children
• Do not give lansoprazole to children.

If you forget to take lansoprazole  
• If you take your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

What Lansoprazole gastro-resistant capsules look like and contents of the pack
• Lansoprazole gastro-resistant capsules are white like and contents of the pack.

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4. POSSIBLE SIDE EFFECTS

Like all medicines, Lansoprazole gastro-resistant capsules can cause side effects, although not everybody gets them.

Stop taking lansoprazole and see a doctor or go to a hospital straightaway if:
• You get swelling of the hands, feet, ankles, face, lips or throat which can cause difficulty in swallowing or breathing. You could also notice itchy, lumpy rash (hives) or nettle rash (urticaria)
• You have itching, peeling or blistering of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. This could be signs of something called Stevens-Johnson syndrome
• You get a blistery rash in which layers of the skin may peal off to leave large areas of raw exposed skin over the body. These could be signs of toxic epidermal necrolysis (TEN)
• You get symptoms such as yellowing of your skin or whites of your eyes, unusual tiredness and flu-like fever. This may be due to inflammation of the liver or changes in the way your liver is working. While these are serious side effects that require urgent medical attention, they are all rare or very rare (affect up to 1 in 1000 people)

Link to your doctor as soon as possible if:
• You get long lasting diarrhoea and keep being sick. This can happen because lansoprazole lowers the natural acid in your stomach which normally helps to kill bacteria. This can lead to stomach ulcers
• You get severe stomach pain which may reach your back and is made worse by food or drink. This could be a sign of peptic ulcers
• You have difficulty in passing water (urine) or notice blood in your urine. This may be due to kidney problems or changes in the way your kidneys are working
• You bruise more easily than usual or you get more infections than usual. This could be due to a blood problem. Your doctor may want to carry out a blood test

The above side effects are all rare or very rare (affect up to 1 in 1000 people)

If any of the following side effects gets serious or lasts longer than a few days, tell your doctor or pharmacist.
Common (affects up to 1 in 10 people)
• Headaches, feeling dizzy or tired, or a general feeling of being unwell
• Diarrhoea, constipation, stomach pains, feeling sick (nausea) or being sick (vomiting), wind
• Dry or sore mouth or throat, bad taste in your mouth
• Skin rash, itching
• Changes in the way your liver is working (shown by a blood test)

Uncommon (affects up to 1 in 100 people)
• Low mood (depression)
• Joint or muscle pain
• Water retention which may cause swelling arms or legs
• Fracture of the hip, wrist or spine (if lansoprazole is used in high doses and over a long period of time)

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Safety Information
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Safety Information
• Do not give lansoprazole to children.

5. HOW TO STORE LANSOPRAZOLE
• Keep this medicine out of the sight and reach of children.
• Do not use this medicine after the expiry date which you will find on the pack.
• Store in the original package.
• Do not store above 30°C.
• Do not throw away any medicines by flushing down a toilet or a sink or by throwing out with your normal household rubbish. Ask your pharmacist how to throw away medicines you no longer use. This will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lansoprazole gastro-resistant capsules contain
The active substance is Lansoprazole. Each 15 mg capsule contains 15 mg Lansoprazole, each 30 mg capsule contains 30 mg Lansoprazole. The other ingredients are hypromellose (E-464), talc (E-553b), titanium dioxide (E-171), macrogolic 4000, gelatin and black ink (Shellac and Black Iron Oxide E-172).

What Lansoprazole gastro-resistant capsules look like and contents of the pack
Lansoprazole 15mg gastro-resistant capsules are white and imprinted with LAN 15. Lansoprazole 30mg gastro-resistant capsules are white and imprinted with LAN 30. They are supplied in blister packs of 28 capsules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder:
Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.
Manufacturer:
Laboratorios Dr Esteve S.A., Sant Marti, S/n, Poligono Industrial la Roca, 08107, Martorell, Barcelona, Spain.

This leaflet was last revised in April 2017

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