1. WHAT PEPTAZOLE IS AND WHAT IT IS USED FOR

The name of your medicine is Peptazole 15mg or 30mg enteric coated pellets filled in capsules (called lansoprazole throughout this leaflet). It belongs to a group of medicines called proton pump inhibitors. Lansoprazole works by lowering the amount of acid in your stomach.

It can be used for:
• Healing ulcers in your stomach or duodenum (gut).
• Healing and preventing ulcers caused by medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). This includes medicines like aspirin, ibuprofen, ketoprofen and piroxicam.
• Gastro-Oesophageal Reflux Disease (GORD). This happens when acid from your stomach escapes into your food pipe (oesophagus) causing damage and inflammation. Lansoprazole can relieve symptoms that can happen with the above conditions and stop them from coming back.

It can also be used to treat:
• The pain of indigestion or heartburn caused by too much acid (acid-related dyspepsia) in your stomach.
• Illnesses, such as Zollinger-Ellison Syndrome, where the stomach makes large amounts of acid. This can lead to diarrhoea and pain in the stomach.

For Peptazole 15 mg:
• Short term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adult. The treatment should not exceed 4 weeks without consulting a doctor.
If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should be instructed to consult a doctor.

2. BEFORE YOU TAKE PEPTAZOLE

Do not take lansoprazole and tell your doctor if:
• You are allergic (hypersensitive) to lansoprazole or any of the other ingredients of these capsules (listed in section 6: Further Information).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
• You are taking a medicine containing atazanavir (used to treat HIV).
Do not take lansoprazole if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Take special care and check with your doctor before taking lansoprazole if:
• You have liver problems your doctor may want to adjust your dose.
• 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.
• If you take lansoprazole on a long-term basis (longer than 1 year) your doctor will probably ask to see you regularly so he can check how well you are doing. Tell your doctor if you notice any new symptoms or if any of your symptoms are getting worse.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking lansoprazole. Do this even if they applied only in the past.

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 hip, wrist or spine.

Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

**Taking Peptazole with other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because lansoprazole can affect the way some other medicines work. Also, some medicines can affect the way lansoprazole works.

In particular, check with your doctor or pharmacist if you are taking any of the following medicines:

• Ketoconazole, itraconazole, rifampicin (used to treat infections).
• Digoxin (used to treat heart problems).
• Theophylline (used to treat asthma).
• Tacrolimus (used to prevent transplant rejection).
• Fluvoxamine (used to treat depression and other psychiatric problems).
• Antacids (used to treat heartburn or acid regurgitation).
• Sucralfate (used for healing ulcers).
• St John’s wort sometimes called Hypericum perforatum (used to treat mild depression).

If you are not sure, talk to your doctor or pharmacist before taking lansoprazole.

**Taking Peptazole with food and drink**

You should take lansoprazole at least 30 minutes before food.

**Pregnancy and breast-feeding**

Talk to your doctor before taking lansoprazole if:

• You are pregnant, think you may be pregnant or are planning to get pregnant.
• You are breast-feeding.
Driving and using machines
You may feel dizzy, tired, sick, have a headache or problems with your eyesight while taking lansoprazole. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE PEPTAZOLE
Always take Peptazole enteric coated pellets filled in capsules exactly as your doctor has told you. The dose will depend on your needs and the illness being treated. Check with your doctor or pharmacist if you are not sure.

Taking your medicine
• Swallow your capsules whole with a glass of water. Do not crush or chew the capsules.
• If you are taking lansoprazole once a day, take it at the same time every morning before breakfast.
• If you are taking lansoprazole twice a day, take the first dose in the morning before breakfast and the second dose in the evening.

The usual doses for adults are:

Stomach ulcers:
• One 30mg capsule every day for 4 weeks.

Ulcers of the duodenum:
• One 30mg capsule every day for 2 weeks to heal the ulcer.
• Your doctor may then decide you need one 15mg capsule every day to stop it coming back.

Ulcers of the stomach and duodenum caused by NSAID:
• One 30mg capsule every day for 4 weeks to heal it.
• Your doctor may then decide to give you one 15mg or 30mg capsule every day to stop the ulcer or your symptoms coming back.
• Your doctor will tell you when to stop taking lansoprazole.

Preventing an ulcer and relief of symptoms while taking NSAID:
• One 15mg or 30mg capsule every day.
• Your doctor will tell you when to stop taking Lansoprazole.

Gastro-oesophageal reflux disease (GORD):
• 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.
• See your doctor once you have completed this course or if your symptoms are not getting better.

**Zollinger-Ellison syndrome:**
• Two 30mg capsules every day to start with.
• Your doctor will then decide the dose which is best for you depending on how you respond to lansoprazole.

For Peptazole 15 mg:
**Short term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adult:**
The recommended dose is 15 mg per day in case of short term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adult. It is classified as a medical product not subjected to medical prescription regarding this indication. It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms. Once complete relief of symptoms has occurred, treatment should be discontinued. The treatment should not exceed 4 weeks without consulting a doctor. If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should be instructed to consult a doctor.

**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 Peptazole than you should**
Tell your doctor or go to your nearest hospital straight away. Remember to take with you any lansoprazole capsules that are left and the pack. This is so the doctor knows what you have taken.

**If you forget to take Peptazole**
If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose.

Do not take a double dose to make up for a forgotten dose.

**Stopping treatment**
Keep taking the medicine until your doctor tells you to stop. Do not stop taking lansoprazole just because you feel better. If you do stop taking lansoprazole your illness may get worse again.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Peptazole enteric coated pellets filled in 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 may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria).
  This may mean you are having an allergic reaction to Peptazole enteric coated pellets filled in capsules.
• You have blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of something called Stevens-Johnson syndrome.
• You get a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. These could be signs of toxic epidermal necrolysis.
• You get symptoms such as: yellowing of your skin or whites of your eyes, tiredness and 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 less than 1 in 1000 people).

Tell 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 would normally help to kill the bacteria there. This, in turn, can lead to stomach infections.
• You get severe stomach pain which may reach through to your back. This could be a sign of pancreatitis.
• You have difficulty in passing water (urine) or you 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 less than 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 less than 1 in 10 people)**
- Headaches, feeling dizzy or tired, or a general feeling of being unwell.
- Diarrhea, constipation, stomach pains, feeling sick (nausea) or being sick (vomiting), wind.
- Dry or sore mouth or throat.
- Skin rash, itching.
- Changes in the way your liver is working (shown by a blood test).

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

**Rare (affects less than 1 in 1000 people)**
- Fever.
- Feeling restless, drowsy or confused.
- Seeing or hearing things which are not there (hallucinations).
- Numbness, tingling, pricking, burning or creeping on the skin (paraesthesia).
- Difficulty sleeping (insomnia).
- Problems with your vision.
- Feeling dizzy, possibly with a "spinning" feeling (vertigo).
- A change in the way things taste, loss of appetite, inflammation of your tongue (glossitis).
- Skin reactions such as burning or pricking feeling under the skin, bruising, red or purple spots which may be itchy or blister.
- Excessive sweating.
• Being more sensitive to the sun than usual.
• Hair loss (alopecia).
• Trembling.
• Feeling tired, faint, dizzy, having pale skin. These could be symptoms of anaemia.
• Swelling of the breasts in men, being unable to get or keep an erection (impotence).
• Candidiasis fungal infection, such as thrush, which may affect your oesophagus (food pipe).

**Very rare (affects less than 1 in 10,000 people)**
• Inflammation of your mouth (stomatitis).
• Colitis (bowel inflammation).
• Changes in test values such as sodium, cholesterol and triglyceride levels.

**Not known (frequency cannot be estimated from the available data)**
• If you are on lansoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
• Possible increased risk of clostridium difficile –associated diarrhea (CDAD) with proton pump inhibitor use especially in hospitalized patients. This diagnosis should be considered for diarrhea that does not improve.

Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.

CDAD has been reported with use of nearly all antibacterial agents.

If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

**5. STORING PEPTAZOLE**

Keep out of the reach and sight of children.

Do not use Peptazole after the expiry date, which is stated on the carton after “EXP”.

Store below 30°C.
6. FURTHER INFORMATION

What Peptazole enteric coated pellets filled in capsules contain

Each Peptazole 15mg enteric coated pellets filled in capsules contain 180mg (equivalent to l anzoprazole 15mg) as active ingredient.

Each Peptazole 30mg enteric coated pellets filled in capsules contain 360mg (equivalent to lanzoprazole 30mg) as active ingredient.

And as excipients:
- Gelatin Caps-Peptazole 15mg in Peptazole 15mg.
- Gelatin Caps-Peptazole 30mg in Peptazole 30mg.

What Peptazole enteric coated pellets filled in capsules look like and contents of the pack

Peptazole 15mg enteric coated pellets filled in capsules are Size no. 2, hard gelatin capsule with opaque medium orange body and cap containing a white to off-white enteric-coated pellets. The capsule is printed with “PEPTAZOL 15mg” in black on both parts.

Peptazole 30mg enteric coated pellets filled in capsules are Size no. 1, two toned gelatin capsule containing a white to off-white pellets. The cap is bluish green and the body is opaque light green. The capsules is printed with “PEPTAZOL 30mg” in white on both parts.

The Marketing Authorization holder and Manufacturer:

SPIMACO
AlQassim pharmaceutical plant
Saudi Pharmaceutical Industries &
Medical Appliance Corporation

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