OMEPRAZOLE 20MG CAPSULES
PL 15764/0029

UKPAR

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LAY SUMMARY

The MHRA granted Strandhaven Ltd (trading as Somex Pharma) a Marketing Authorisation (licence) for the medicinal product Omeprazole 20mg Capsules (PL 15764/0029). This is a prescription only medicine (POM) for the treatment of reflux oesophagitis and oesophageal reflux disease, acid indigestion, ulcers and excess stomach acid. It is also used for the prevention of ulcers and acid aspiration.

Omeprazole 20mg Capsules contain the active ingredient omeprazole which is a proton-pump inhibitor.

This application is a duplicate of a previously granted application for Omeprazole 20mg Capsules (Laboratorios Davur S.L) initially granted to Rockspring Healthcare Ltd (a change of ownership occurred on 05 September 2005). As such, these products can be used interchangeably.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of taking Omeprazole 20mg Capsules outweigh the risks, hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Omeprazole 20mg Capsules to Strandhaven Ltd (trading as Somex Pharma) on 17 December 2007. This product is a prescription only medicine.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC as amended, referring to Omeprazole 20mg Capsules (Laboratorios Davur S.L) initially granted to Rockspring Healthcare Ltd.

No new data was submitted nor was it necessary for this simple application since the data are identical to that of the previously granted reference product. As the reference product was granted prior to the introduction of current legislation, a Public Assessment Report (PAR) was not generated for it.

The product contains the active ingredient omeprazole which is a selective proton-pump inhibitor that binds to H^+/K^+ ATPase of the parietal cells of the stomach, increasing the pH of and reducing the volume of basal and stimulus-induced acid secretion.

PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as a capsule containing 20mg of the active pharmaceutical ingredient omeprazole. The excipients present are sugar spheres, sodium starch glycolate, sodium laurilsulfate, povidone, potassium oleate, oleic acid, hypromellose, methacrylic acid and ethyl acrylate copolymer, triethyl citrate, titanium dioxide and talc. Gelatin, titanium dioxide, quinoline yellow, indigo carmine and erythrosine are present in the capsule shell. Shellac, ethyl alcohol anhydrous, isopropyl alcohol, n-butyl alcohol, polyvinylpyrrolidone, propylene glycol, sodium hydroxide and titanium dioxide are present in the printing ink.

Omeprazole 20mg Capsules are presented in HDPE bottles with polypropylene caps in packs of 28 capsules.

DRUG SUBSTANCE

Omeprazole

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification based on the European Pharmacopoeia monograph is provided for omeprazole.

Analytical methods have been validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data are provided for three batches and comply with the proposed specification.

Omeprazole is stored in appropriate packaging. Satisfactory specifications have been provided for the packaging components.

Stability data have been generated supporting a retest period of 2 years when stored in the proposed packaging at 2-8°C.

DRUG PRODUCT

Other ingredients

All excipients used in the manufacture of the tablets are routinely tested for compliance with current relevant international standards.

Satisfactory certificates of analysis have been provided for all excipients.

Gelatin is the only excipient that contains material of animal or human origin. A Transmissible Spongiform Encephalopathies (TSE) Certificate has been provided for gelatin confirming that the risk of transmitting TSEs is sufficiently low.

Manufacture
A full description and a detailed flow-chart of the manufacturing method including in-process control steps has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out and the results are satisfactory.

Finished product specification
The proposed finished product specification is acceptable and the analytical methods used have been suitably validated. Batch analysis data have demonstrated compliance with the proposed release specification. Suitable reference standards were used.

Container Closure System
Satisfactory specifications and certificates of analysis have been provided for the packaging components. All primary product packaging complies with EU legislation regarding contact with food.

Stability
Finished product stability data support the proposed shelf-life of 3 years with storage conditions “Do not store above 30°C, Store in the original package, Keep the bottle tightly closed.”

Bioequivalence/bioavailability
A bioequivalence study was not required for this application.

SPC, PIL and Labels
The SPC and labels are pharmaceutically acceptable.

A patient information leaflet (PIL) has been submitted to the MHRA along with a bridging report which refers to the results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC performed on the PIL of a similar product. The results indicate that the applicant’s PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

CONCLUSION

It is recommended that a Marketing Authorisation should be granted for this application.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

As this is a duplicate application, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the reference product and as such it has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to the previously granted application for Omeprazole 20mg Capsules in which the applicant provided clinical data.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product has been shown to be interchangeable with the innovator product. Clinical experience with omeprazole is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1 The MHRA received the Marketing Authorisation application on 16 November 2005.

2 Following standard checks and communication with the applicant, the MHRA considered the application valid on 15 December 2005.

3 Following assessment of the application, the MHRA requested further information relating to the quality dossier on 14 July 2006 and 26 October 2007.

4 The applicant responded to the MHRA's requests, providing further information on 20 August 2007 and 13 November 2007 for the quality sections.

5 The application was determined on 17 December 2007.

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STEPS TAKEN AFTER AUTHORISATION – SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Omeprazole 20 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains omeprazole 20 mg.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Capsule, hard containing gastro-resistant granules
Each capsule consists of an orange body and blue cap and contains white to beige granules marked with O20.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Treatment of reflux oesophagitis disease. In reflux oesophagitis the majority of patients are healed after 4 weeks. Symptom relief is rapid.

2. Treatment of duodenal and benign gastric ulcers including complicating NSAID therapy.

3. Relief of reflux-like symptoms (e.g. heartburn) and/or ulcer-like symptoms (e.g. epigastric pain) associated with acid-related dyspepsia.

4. Treatment and prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers and gastroduodenal erosions in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.

5. Relief of associated dyspeptic symptoms.

6. *Helicobacter pylori* eradication: When used with in combination with antibiotics, Omeprazole proves effective in the eradication of *Helicobacter pylori* (*Hp*) in peptic ulcer disease.

7. Prophylaxis of acid aspiration.

8. Zollinger-Ellison syndrome.

4.2 Posology and method of administration

Oesophageal reflux disease including reflux oesophagitis:

The usual starting dose is 20 mg omeprazole taken once a day for 4 weeks. For those patients not fully healed after the initial 4 week course, healing usually occurs during a further 4-8 weeks treatment.

Omeprazole has also been used in a dose of 40mg once a day in patients with reflux oesophagitis refractory to other therapy. Healing usually occurred within 8 weeks. Continuation of therapy can be considered at a dosage of 20 mg once daily.

Acid reflux disease:

For long-term management, a dose of 10 mg once daily is recommended, increasing to 20 mg if symptoms return.

Duodenal and benign gastric ulcers:

The usual dose is 20 mg omeprazole once daily. With duodenal ulcers, the majority of patients usually are healed after 4 weeks of treatment. The majority of patients with benign gastric ulcer are healed after 8 weeks. In severe or recurrent cases the dose may be increased to 40 mg omeprazole daily. For patients with a history of recurrent duodenal ulcer, long term therapy is recommended at a dosage of 20 mg omeprazole once daily.

To prevent recurrence, in patients with duodenal ulcer, the recommended dose is omeprazole 10 mg, once daily, increasing to 20 mg, once daily if symptoms return.

The following groups of patients are at risk from recurrent ulcer relapse: those with *Helicobacter pylori* infection, younger patients (<60 years), those whose symptoms persist for more than one year and smokers. These patients will require initial long-term therapy with omeprazole 20 mg once daily, reducing to 10 mg once daily, if necessary.

Acid-related dyspepsia:

Usual dosage is 10 mg or 20 mg omeprazole once daily for 2 – 4 weeks depending on the severity and persistence of symptoms.

If the patient does not respond to treatment after 4 weeks or who relapse shortly after treatment, then the patient should be investigated.

For the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastroduodenal erosions:

The recommended dosage of omeprazole is 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment.

For the prophylaxis of NSAID-associated gastric ulcers, duodenal ulcers, gastroduodenal erosions and dyspeptic symptoms in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment:
The recommended dosage is 20 mg omeprazole taken once a day.

***Helicobacter pylori (Hp)* eradication regimens in peptic ulcer disease:**
Omeprazole is recommended at a dose of 40 mg once daily or 20 mg twice daily concomitant with antimicrobial agents as detailed below:

Triple therapy regimens in duodenal ulcer disease:
Omeprazole and the following antimicrobial combinations;

Amoxicillin 500 mg and metronidazole 400 mg both three times a day for one week.

or

Clarithromycin 250 mg and metronidazole 400 mg (or tinidazole 500 mg) both twice a day for one week.

or

Amoxicillin 1 g and clarithromycin 500 mg both twice a day for one week.

Dual therapy regimens in duodenal ulcer disease
Omeprazole and amoxicillin 750 mg to 1 g twice daily for two weeks. Alternatively, omeprazole and clarithromycin 500 mg three times a day for two weeks.

Dual therapy regimens in gastric ulcer disease:
Omeprazole and amoxicillin 750 mg to 1 g twice daily for two weeks.

In each regimen if symptoms return and the patient tests positive for *Hp*, therapy may be repeated or one of the alternative regimens can be used; if the patient is *Hp* negative then see dosage instructions for acid reflux disease.

To ensure healing in patients with active peptic ulcer disease, see further dosage recommendations for duodenal and benign gastric ulcer.

Prophylaxis of acid aspiration:
For patients considered to be at risk of aspiration of the gastric contents during general anaesthesia, the recommended dosage is omeprazole 40 mg on the evening before surgery followed by a further 40 mg 2 – 6 hours prior to surgery.

Zollinger-Ellison syndrome:
The initial starting dose is omeprazole 60 mg once a day. The dosage should be adjusted individually and treatment continued as long as clinically indicated. More than 90% of patients with severe disease and inadequate response to other therapies have been effectively controlled on doses of 20 – 120 mg daily. With doses above 80 mg daily, the dose should be divided and given twice daily.

Elderly:
Dose adjustment is not required in the elderly.

Children:
There is limited experience of the use of Omeprazole in children. In children over 2 years who present with severe ulcerating reflux oesophagitis, Omeprazole Capsules are recommended for symptomatic relief within the dose range of 0.7 – 1.4 mg/kg daily, to a maximum of 40 mg/day, for 4 – 12 weeks. Data suggest that approximately 65% of children will experience pain relief with this dose regimen.

Treatment should be initiated by a hospital based paediatrician.

For children aged 2 – 6 years, the capsule may be opened, see section: "Patients with Swallowing Difficulties."

Impaired renal function:
Dose adjustment is not required in patients with impaired renal function.

Impaired hepatic function:
As bioavailability and half-life can increase in patients with impaired hepatic function, the dose requires adjustment with a maximum daily dose of 20 mg.

Patients with swallowing difficulties:
The capsules may be opened and the contents either swallowed alone or suspended in a small amount of fruit juice or yoghurt after gentle mixing. The dispersion should be taken immediately or within 30 minutes. Actual capsules may be sucked and then swallowed. It is important that the contents of the capsules should not be crushed or chewed.

4.3 Contraindications

Known hypersensitivity to omeprazole or to any of the other constituents of the formulation.

When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Omeprazole 20 mg Capsules is commenced, as treatment may alleviate symptoms and delay diagnosis.

4.4 Special warnings and precautions for use

Decreased gastric acidity due to any means, including proton-pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid-reducing drugs may lead to a slightly increased risk of gastrointestinal infections, such as *Salmonella* and *Campylobacter*.

This product contains sucrose and therefore patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the decreased intragastric acidity the absorption of ketoconazole or itraconazole may be reduced during omeprazole treatment as it is during treatment with other acid secretion inhibitors.

As omeprazole is metabolised in the liver through cytochrome P450, it can prolong the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be required. However, concomitant treatment with Omeprazole 20 mg once daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. Similarly, concomitant treatment with Omeprazole 20 mg daily did not change coagulation time in patients on continuous treatment with warfarin.

Plasma concentrations of omeprazole and clarithromycin are increased during concomitant administration. This is considered to be a useful interaction during *H. pylori* eradication. There is no interaction with metronidazole or amoxicillin. These antimicrobials are used concomitantly with omeprazole for the eradication of *H. pylori*.

There is no evidence of an interaction with phenacetin, theophylline, caffeine, propranolol, metoprolol, ciclosporin, lidocaine, quinidine, estradiol, or antacids. The absorption of Omeprazole 20 mg Capsules is not affected by alcohol or food.

There is no evidence of an interaction with piroxicam, diclofenac or naproxen. This is considered useful when patients are required to continue these treatments.

Simultaneous treatment with omeprazole and digoxin in healthy subjects lead to a 10% increase in the bioavailability of digoxin as a consequence of the increased intragastric pH.

4.6 Pregnancy and lactation

Results from three epidemiological studies have revealed no evidence of adverse events of omeprazole on pregnancy or on the health of the foetus / newborn child. Omeprazole 20 mg can be used during pregnancy.

Omeprazole is excreted into breast milk but is unlikely to influence the child when used in therapeutic doses.

4.7 Effects on ability to drive and use machines

No foreseen effects.

4.8 Undesirable effects

Omeprazole 20 mg Capsules are well tolerated and adverse reactions have generally been mild and reversible. The following have been reported as adverse events in clinical trials or reported from routine use but in many cases a relationship to treatment with omeprazole has not been established.

The following definitions of frequencies are used:

Common ≥ 1/100

Uncommon ≥ 1/1000 and < 1/100

Rare < 1/1000

Common	*Central and peripheral nervous system:* *Gastrointestinal:*	Headache Diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence
Uncommon	*Central and peripheral nervous system:* *Hepatic:* *Skin:* *Other:*	Dizziness, paraesthesia, light headedness, feeling faint, somnolence, insomnia and vertigo Increased liver enzymes Rash and/or pruritus Urticaria Malaise
Rare	*Central and peripheral nervous system:* *Endocrine:*	Reversible mental confusion, agitation, aggression, depression and hallucinations, predominantly in severely ill patients Gynaecomastia

	Gastrointestinal:	Dry mouth, stomatitis and gastrointestinal candidiasis
	Haematological:	Leukopenia, thrombocytopenia, Agranulocytosis and pancytopenia
	Hepatic:	Encephalopathy in patients with pre-existing severe liver disease; hepatitis with or without jaundice, hepatic failure
	Musculoskeletal:	Arthritic and myalgic symptoms and muscular weakness
	Reproductive system and breast disorders:	Impotence
	Skin:	Photosensitivity, bullous eruption erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, alopecia
	Other:	Hypersensitivity reactions e.g. angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock. Increased sweating, peripheral oedema, blurred vision, taste disturbance and hyponatraemia.

4.9 Overdose

Rare reports have been received of overdosage with omeprazole. Doses of up to 560 mg have been described and occasional reports have been received when single oral doses have been reached up to 2400 mg, which is 120 times the recommended clinical dose. Overdosage of omeprazole is reported to be associated with nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache. Single cases of apathy, depression and confusion have been described.

The symptoms described in connection with omeprazole overdosage have been transient and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses and no specific treatment is needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A02B C01 - Drugs for peptic ulcers and gastro-oesophageal reflux disease - Proton Pump inhibitors.

Omeprazole reduces gastric acid secretion through a unique mechanism of action. It is a specific inhibitor of the gastric proton pump in the parietal cell. It is rapidly acting and produces reversible inhibition of gastric acid secretion with once daily dosing.

An oral dose of 20 mg once a day produces a rapid and effective inhibition of gastric acid secretion with maximum effect being achieved within 4 days of treatment. In duodenal ulcer patients, a mean decrease of approximately 80% in 24-hour intragastric acidity is then maintained, with the mean decrease in peak acid output after pentagastrin stimulation being about 70%, twenty-four hours after dosing with Omeprazole 20 mg Capsules.

Clinical data for omeprazole in the prophylaxis of NSAID induced gastroduodenal lesions are derived from clinical studies of up to 6 months duration.

Helicobacter pylori (*Hp*) is associated with acid peptic disease including duodenal ulcer and gastric ulcer in which about 95% and 80% of patients respectively are infected with this bacterium. *Hp* is implicated as a major contributing factor in the development of gastritis and ulcers in such patients. Recent evidence also suggests a causative link between *Hp* and gastric carcinoma.

Omeprazole has been shown to have a bactericidal effect on *Hp* in vitro.

Eradication of *Hp* with omeprazole and antimicrobials is associated with rapid symptom relief, high rates of healing of any mucosal lesions, and long-term remission of peptic ulcer disease thus reducing complications such as gastrointestinal bleeding as well as the need for prolonged anti-secretory treatment.

In recent clinical data in patients with acute peptic ulcer omeprazole *Hp* eradication therapy improved patients' quality of life.

During long-term treatment an increased frequency of gastric glandular cysts has been reported. These changes are a physiological consequence of pronounced inhibition of acid secretion. The cysts are benign and appear to be reversible. No other treatment related mucosal changes have been observed in patients treated continuously with omeprazole for periods up to 5 years.

Site and mechanism of action

Omeprazole is a weak base and is concentrated and converted to the active form in the acid environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H^+, K^+-ATPase - the proton pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for effective inhibition of both basal acid secretion and stimulated acid secretion irrespective of the stimulus.

All pharmacodynamic effects observed are explained by the effect of omeprazole on acid secretion.

5.2 Pharmacokinetic properties

Absorption and distribution

Omeprazole is acid labile and is administered orally as enteric-coated granules in capsules. Absorption takes place in the small intestine and is usually completed within 3 – 6 hours. The systemic bioavailability of omeprazole from a single oral dose is approximately 35%. After repeated once-daily administration, the bioavailability increases to about 60%. Concomitant intake of food has no influence on the bioavailability. The plasma protein binding of omeprazole is about 95%.

Elimination and metabolism

The average half-life of the terminal phase of the plasma concentration-time curve is approximately 40 minutes. There is no change in half-life during treatment. The inhibition of acid secretion is related to the area under the plasma concentration-time curve (AUC) but not to the actual plasma concentration at a given time.

Omeprazole is entirely metabolised, mainly in the liver. Identified metabolites in plasma are the sulfone, the sulfide and hydroxy-omeprazole, these metabolites have no significant effect on acid secretion. About 80% of the metabolites are excreted in the urine and the rest in the faeces. The two main urinary metabolites are hydroxy-omeprazole and the corresponding carboxylic acid.

The systemic bioavailability of omeprazole is not significantly altered in patients with reduced renal function. The area under the plasma concentration-time curve is increased in patients with impaired liver function, but no tendency to accumulation of omeprazole has been found.

Children

Available data from children (1 year and older) suggest that the pharmacokinetics within the recommended doses are similar to those reported in adults. At steady state, lower plasma levels of omeprazole were seen in some children.

5.3 Preclinical safety data

Animal toxicity:

Gastric ECL-cell hyperplasia and carcinoids, have been observed in life-long studies in rats treated with omeprazole or subjected to partial fundectomy. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition, and not from a direct effect of any individual drug.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar spheres
Sodium starch glycolate
Sodium laurilsulfate
Povidone
Potassium oleate
Oleic Acid
Hypromellose
Methacrylic acid - ethyl acrylate (1:1)
Triethyl citrate
Titanium dioxide
Talc

Capsule
Gelatin
Titanium dioxide (E171)
Quinoline yellow (E104)
Indigo carmine – FD&C Blue No.2 (E132)
Erythrosine – FD&C Red No.3 (E127)

Printing Ink
Shellac
Ethyly Alcohol anhydrous
Isopropyl Alcohol
N-Butyl Alcohol
Polyvinylpyrrolidone
Propylene glycol
Sodium Hydroxide
Titanium Dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30ºC. Store in the original package. Keep the bottle tightly closed.

6.5 Nature and contents of container

HDPE bottle and polypropylene cap with integral silica gel dessicant

Each pack contains 28 capsules.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Strandhaven Limited T/A Somex Pharma
600 High Road
Seven Kings
Ilford
Essex IG3 8BS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 15764/0029

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/12/2007

10 DATE OF REVISION OF THE TEXT

17/12/2007

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET
Omeprazole 20mg Capsules

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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 you doctor or pharmacist

In this Leaflet

1. WHAT OMEPRAZOLE 20 MG CAPSULES ARE AND WHAT THEY ARE USED FOR

The active ingredient, omeprazole, belongs to a group of medicines called "proton pump inhibitors". It works by reducing the production of acid in your stomach.
Omeprazole is used to treat the following conditions:
- *Reflux oesophagitis and Oesophageal reflux disease*, where acid from the stomach escapes into the food pipe causing pain, inflammation and heartburn.
- Acid indigestion (*dyspepsia)* which can cause stomach pain and/or discomfort.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer). For patients who have had previous trouble with an ulcer and need to continue therapy with a non-steroidal anti-inflammatory drug (NSAID), omeprazole can heal ulcers or prevent an ulcer developing. In such patients, omeprazole protects the stomach or duodenum whilst they are taking NSAIDs.
- Ulcers which are infected with bacteria called *Helicobacter pylori.*
- Prevention of damage to the lungs caused by breathing in stomach fluids (acid aspiration), e.g. before an operation.
- *Zollinger-Ellison syndrome,* when excess stomach acids are produced due to a growth in the pancreas.

2. BEFORE YOU TAKE OMEPRAZOLE 20 MG CAPSULES

If any of the following applies to you, speak to your doctor or pharmacist before you start taking Omeprazole Capsules as they may not be suitable for you.

Do not take Omeprazole 20 mg Capsules:
- If you are allergic (hypersensitive) to Omeprazole or any of the other ingredients of Omeprazole 20 mg Capsules.
- If you have a gastric ulcer and the possibility of malignancy has not been ruled out.

Take special care with Omeprazole 20 mg Capsules: It is important to talk to your doctor if you have any of the following conditions:
- If you have any liver problems
- If you have an intolerance to some sugars

Taking other medicines:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.
- Diazepam (for your nerves). Elimination of diazepam may be reduced during treatment with omeprazole.
- Phenytoin (for epilepsy). Elimination of phenytoin may be reduced during treatment with omeprazole.
- Warfarin (for thinning of the blood). Elimination of warfarin may be reduced during treatment with omeprazole.
- Digoxin (for the heart). The bioavailablity of digoxin can increase during treatment with omeprazole.
- Ketoconazole or itraconazole (for fungal infections). Absorption of ketoconazole or itraconazole may be reduced during treatment with omeprazole.

Pregnancy and breast-feeding:
Omeprazole 20 mg Capsules can be used during pregnancy and if you are breast-feeding.

Driving and using machines:
Your medicine does not usually affect your ability to drive or operate machinery.

Other precautions you should take:
If you are going to have an operation and anaesthetic (including at the dentist) tell your doctor or dentist that you are taking Omeprazole 20 mg Capsules.

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 OMEPRAZOLE 20 MG CAPSULES

Your doctor has decided on the dose which is suited to you. The length of your course of treatment will depend on what condition you are suffering from. Always take Omeprazole 20 mg Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You can take your capsules with food or on an empty stomach at any time of the day. The capsules should not be chewed or crushed. They should be swallowed whole with a drink of water. If you have trouble swallowing the capsules, open the capsule and mix the granules with some fruit juice or yoghurt and then drink immediately.

Treatment for heartburn (Reflux oesophagitis and oesophageal reflux disease)
The usual dose for adults is 20 mg omeprazole taken once a day for 4 weeks. Your doctor may ask you to continue taking the capsules or increase the dose depending on how you respond to treatment. To stop your symptoms returning your doctor may tell you to continue to take 20 mg Omeprazole or reduce the dose to 10mg. For children the usual starting dose will be dependent on their weight and treatment should be given for a period of 4 - 12 weeks.

Relief of Acid Indigestion (Dyspepsia)
The usual dose is 10 mg or 20 mg once a day for a period of 2 - 4 weeks. Your doctor will tell you how long to take your capsules for. If you do not experience any improvement in your symptoms you should return to your doctor.

Treatment of ulcers in the upper part of the intestine (duodenal ulcer) and stomach (gastric ulcer)
The usual dose is 20 mg omeprazole once a day for a period of 4 - 8 weeks depending on your symptoms. Your doctor may increase the dose depending on how you respond to treatment. To stop your ulcer coming back, the

usual dose is omeprazole 10 mg once daily unless your symptoms return. If your symptoms return, your doctor may increase the dose.

Treatment and prevention of stomach ulcers, duodenal ulcers and associated symptoms caused by NSAIDs
If you have previously had trouble with an ulcer and need to continue taking a NSAID the recommended dose is omeprazole 20 mg once daily. Your doctor will advise how long you need to take the capsules for.

Treatment of Ulcers caused by infection with the bacteria called Helicobacter Pylori
The usual dose is omeprazole 40 mg once a day or 20 mg taken twice a day for a period of 1 - 2 weeks. Your doctor will also tell you to take one or two of the following antibiotics; amoxicillin, clarithromycin, metronidazole or tinidazole. Follow the directions for taking your medicine very carefully and if you are unsure about anything, ask your doctor or pharmacist.

Before a hospital operation when you are to be given a general anaesthetic
The usual dose is omeprazole 40 mg taken the evening before surgery, and another 40 mg dose two to six hours before surgery.

Zollinger - Ellison Syndrome
The usual starting dose is omeprazole 60 mg once a day. If the dose is more than 80 mg a day, half the dose should be taken in the morning and half at night. Your doctor will tell you how many capsules to take and when to take them.

If you take more Omeprazole 20 mg Capsules than you should:
If you (or someone else) accidentally take too many Omeprazole 20 mg Capsules, contact your doctor or pharmacist immediately.

If you forget to take Omeprazole 20 mg Capsules:
If you forget to take a dose, take it as soon as you remember. If it is nearly time for your next dose just take the next dose and forget about the one you missed. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Omeprazole 20 mg Capsules:
Always contact you doctor or pharmacist before you stop taking Omeprazole 20 mg Capsules. Stopping the treatment early can cause the problem to come back.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Omeprazole 20 mg Capsules can cause side effects, although not everybody gets them. These are usually mild and go away when you stop taking this medicine.

If the following happens, stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:
- An allergic reaction (angioedema): swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Side effects sometimes seen are:
Common - more than one in a hundred people but less than one in ten:
- headache, diarrhoea, constipation, abdominal pain, nausea, vomiting and flatulence.

Uncommon - more than one in a thousand people but less than on in a hundred:
- Dizziness, burning, prickling, tickling, tingling, light headedness, feeling faint, insomnia, vertigo, sleepiness, increased liver enzymes, rash, itching and general discomfort.

Rare - more than one in ten thousand people but less than one in a thousand:
- mental confusion, agitation, aggression, depression, hallucinations, larger breasts, dry mouth, sensitivity to light, sore joints and muscles, increased sweating, swollen limbs, blurred vision, taste disorders, low blood sodium, swelling and soreness of the mouth and throat, wheezing, hair loss, impotence, slight increase in the risk of gut infection, kidney or liver problems, reduced blood cells, severe skin reactions

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.

5. HOW TO STORE OMEPRAZOLE 20 MG CAPSULES

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Omeprazole 20 mg Capsules after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of the 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 Omeprazole 20 mg Capsules contains
- The active substance is omeprazole and each capsule contains 20 mg of omeprazole as gastro resistant granules.
- The other ingredients are sugar spheres, sodium starch glycolate, sodium laurilsulfate, povidone, potassium oleate, oleic acid, hypromellose, methacrylic acid - ethyl acrylate copolymer (1:1), triethyl citrate, titanium dioxide and talc. The capsule coating also contains gelatin, titanium dioxide (E171), quinoline yellow (E104), indigo carmine (E132) and erythrosine (E127). The printing ink contains shellac, polyvinylpyrrolidone, propylene glycol, sodium hydroxide and titanium dioxide (E171).

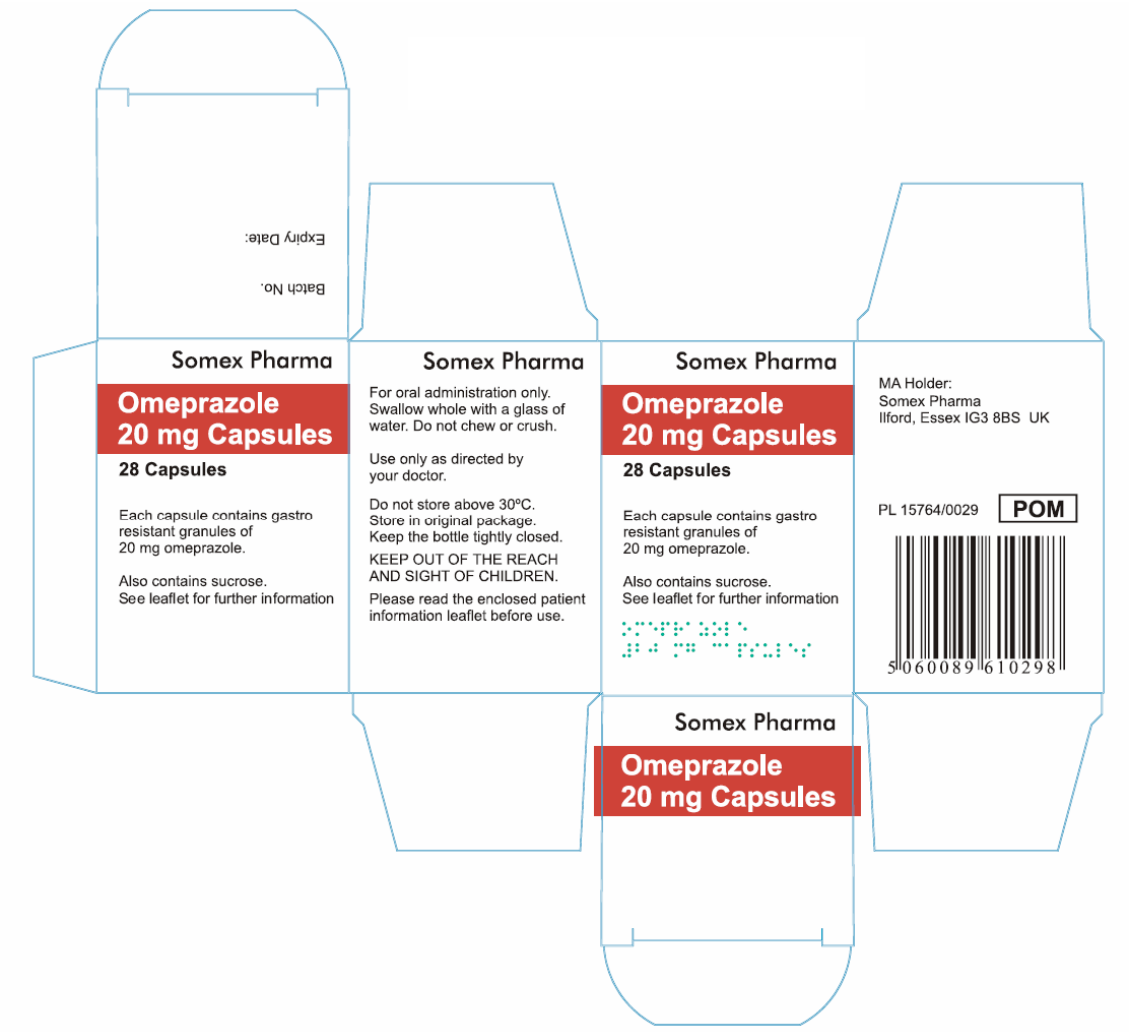
What Omeprazole 20 mg Capsules look like and contents of the pack
Each capsule has an orange body and blue cap and is marked with O20. The capsule contains white to beige gastro-resistant granules.

Omeprazole 20 mg Capsules are available in bottles of 28 capsules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Somex Pharma,
600 High Road,Seven Kings
Ilford ,Essex IG3 8BS
Manufacturer: Laboratorios Belmac S.A., Poligono Industrial Malpica, calle C, 50016 Zaragoza, Spain.

This leaflet was last updated in April 2006

LABELLING



Omeprazole 20 mg Capsules
28 capsules
Each capsule contains gastro resistant granules of 20 mg omeprazole. Also contains sucrose.
MA Holder: Somex Pharma,
Ilford, IG3 8BS UK

For oral administration only. Swallow whole with a glass of water. Do not chew or crush. Use only as directed by your doctor. Do not store above 30ºC. Store in the original package. Keep the bottle tightly closed. KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN. Batch Expiry
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