

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg

Composition:

Each capsule contains:
Omeprazole USP 20 mg
(As enteric coated granules)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

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1. WHAT OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg IS AND WHAT IT IS USED FOR

Omeprazole Delayed Release Capsules USP represents a new trend in the treatment of peptic ulcer and allied conditions whereby the final step of gastric acid secretion is inhibited irrespective of the stimulus. Omeprazole Delayed Release Capsules USP acts specifically by inhibiting the H⁺/K⁺ ATPase enzyme system (proton pump) at the secretory surface of the gastric parietal cells, blocking thereby the final transport of hydrogen ions into the gastric lumen, and thus inhibiting effectively both basal and stimulated acid secretion. Omeprazole Delayed Release Capsules USP has also antimicrobial activity against *Helicobacter pylori*, by selective inhibition of *H. pylori* urease, which is necessary for gastric colonization. Omeprazole Delayed Release Capsules USP has no effect on acetylcholine or histamine receptors. Omeprazole Delayed Release Capsules USP is rapidly absorbed following oral administration and its absorption is not affected by food, but it is dose-dependent. Omeprazole, the active ingredient of Omeprazole Delayed Release Capsules USP, is acid-labile; therefore, Omeprazole Delayed Release Capsules USP capsules have been specially formulated in an attempt to improve bioavailability from the gastrointestinal tract. Bioavailability of Omeprazole Delayed Release Capsules USP may be increased in elderly patients and in patients with impaired hepatic function, but is not markedly affected in patients with renal impairment. Following absorption, Omeprazole Delayed Release Capsules USP is distributed in tissues, particularly gastric parietal cells. It is almost completely metabolized in the liver, primarily by cytochrome P450 enzyme system. It has a rapid onset of action (within one hour) and a rapid elimination, mostly in urine. Although the elimination half-life from plasma is short, being reported to be about 0.5-3 hours, its duration of action with regard to inhibition of acid secretion is much longer allowing it to be used in a once-daily dosing. Omeprazole Delayed Release Capsules USP is highly bound (about 95%) to plasma proteins.

Omeprazole Delayed Release Capsules USP is indicated for:

Peptic ulcer: short and long term treatment of active benign gastric and active duodenal ulcers, including peptic ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAID) as well as with *Helicobacter pylori* infection. Gastro-oesophageal reflux disease: short and long term treatment of severe erosive oesophagitis associated with gastro-oesophageal reflux disease, as well as management of acid-related dyspepsia (symptomatic gastro-oesophageal reflux disease). Zollinger-Ellison syndrome: management of pathologic gastric hypersecretion associated with Zollinger-Ellison syndrome (including cases resistant to other treatment). Acid aspiration: prophylaxis of acid aspiration during general anaesthesia (through gastric acid reduction).

2. BEFORE YOU USE OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg.

Do not use OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg

- If you or your child have a known **allergic reaction to Omeprazole**, to any of the other **ingredients** of this medicine listed in Section 6.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using **OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg**

Warnings and Precautions

In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis.

Co-administration of atazanavir with proton pump inhibitors is not recommended (see section 4.5). If the combination of atazanavir with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g. virus load) is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir; omeprazole 20 mg should not be exceeded.

Omeprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.

Omeprazole is a CYP2C19 inhibitor. When starting or ending treatment with omeprazole, the potential for interactions with drugs metabolised through CYP2C19 should be considered. An interaction is observed between clopidogrel and omeprazole. The clinical relevance of this interaction is uncertain. As a precaution, concomitant use of omeprazole and clopidogrel should be discouraged.

Some children with chronic illnesses may require long-term treatment although it is not recommended.

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with PPIs like omeprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics), health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly

or in presence of other recognised risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Omeprazole capsules contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

As in all long-term treatments, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance.

Interference with laboratory tests

Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, omeprazole treatment should be stopped for at least 5 days before CgA measurements (see section 5.1 in the SPC). If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping Omeprazole Capsules. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Other medicines and OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg

Effects of omeprazole on the pharmacokinetics of other active substances

Active substances with pH dependent absorption

The decreased intragastric acidity during treatment with omeprazole might increase or decrease the absorption of active substances with a gastric pH dependent absorption.

Nelfinavir, atazanavir

The plasma levels of nelfinavir and atazanavir are decreased in case of co-administration with omeprazole.

Concomitant administration of omeprazole with nelfinavir is contraindicated. Co-administration of omeprazole (40 mg once daily) reduced mean nelfinavir exposure by ca. 40% and the mean exposure of the pharmacologically active metabolite M8 was reduced by ca. 75–90%. The interaction may also involve CYP2C19 inhibition.

Concomitant administration of omeprazole with atazanavir is not recommended. Concomitant administration of omeprazole (40 mg once daily) and atazanavir 300 mg/ritonavir 100 mg to healthy volunteers resulted in a 75% decrease of the atazanavir exposure. Increasing the atazanavir dose to 400 mg did not compensate for the impact of omeprazole on atazanavir exposure. The co-administration of omeprazole (20 mg once daily) with atazanavir 400 mg/ritonavir 100 mg to healthy volunteers resulted in a decrease of approximately 30% in the atazanavir exposure as compared to atazanavir 300 mg/ritonavir 100 mg once daily.

Digoxin

Concomitant treatment with omeprazole (20 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10%. Digoxin toxicity has been rarely reported. However caution should be exercised when omeprazole is given at high doses in elderly patients. Therapeutic drug monitoring of digoxin should be then be reinforced.

Clopidogrel

In a crossover clinical study, clopidogrel (300 mg loading dose followed by 75 mg/day) alone and with omeprazole (80 mg at the same time as clopidogrel) were administered for 5 days. The exposure to the active metabolite of clopidogrel was decreased by 46% (Day 1) and 42% (Day 5) when clopidogrel and omeprazole were administered together. Mean inhibition of platelet aggregation (IPA) was diminished by 47% (24 hours) and 30% (Day 5) when clopidogrel and omeprazole were administered together. In another study it was shown that administering clopidogrel and omeprazole at different times did not prevent their interaction that is likely to be driven by the inhibitory effect of omeprazole on CYP2C19. Inconsistent data on the clinical implications of this PK/PD interaction in terms of major cardiovascular events have been reported from observational and clinical studies.

Other active substances

The absorption of posaconazole, erlotinib, ketoconazole and itraconazole is significantly reduced and thus clinical efficacy may be impaired. For posaconazole and erlotinib concomitant use should be avoided.

Active substances metabolised by CYP2C19

Omeprazole is a moderate inhibitor of CYP2C19, the major omeprazole metabolising enzyme. Thus, the metabolism of concomitant active substances also metabolised by CYP2C19, may be decreased and the systemic exposure to these substances increased. Examples of such drugs are R-warfarin and other vitamin K antagonists, cilostazol, diazepam and phenytoin.

Cilostazol

Omeprazole, given in doses of 40 mg to healthy subjects in a cross-over study, increased C_{max} and AUC for cilostazol by 18% and 26% respectively, and one of its active metabolites by 29% and 69% respectively.

Phenytoin

Monitoring phenytoin plasma concentration is recommended during the first two weeks after initiating omeprazole treatment and, if a phenytoin dose adjustment is made, monitoring and a further dose adjustment should occur upon ending omeprazole treatment.

Unknown mechanism

Saquinavir

Concomitant administration of omeprazole with saquinavir/ritonavir resulted in increased plasma levels up to approximately 70% for saquinavir associated with good tolerability in HIV-infected patients.

Tacrolimus

Concomitant administration of omeprazole has been reported to increase the serum levels of tacrolimus. A reinforced monitoring of tacrolimus concentrations as well as renal function (creatinine clearance) should be performed, and dosage of tacrolimus adjusted if needed.

Methotrexate

When given together with proton pump inhibitors, methotrexate levels have been reported to increase in some patients. In high-dose methotrexate administration a temporary withdrawal of omeprazole may need to be considered.

Effects of other active substances on the pharmacokinetics of omeprazole

Inhibitors CYP2C19 and/or CYP3A4

Since omeprazole is metabolised by CYP2C19 and CYP3A4, active substances known to inhibit CYP2C19 or CYP3A4 (such as clarithromycin and voriconazole) may lead to increased omeprazole serum levels by decreasing omeprazole's rate of metabolism. Concomitant voriconazole treatment resulted in more than doubling of the omeprazole exposure. As high doses of omeprazole have been well-tolerated adjustment of the omeprazole dose is not generally required. However, dose adjustment should be considered in patients with severe hepatic impairment and if long-term treatment is indicated.

Inducers of CYP2C19 and/or CYP3A4

Active substances known to induce CYP2C19 or CYP3A4 or both (such as rifampicin and St John's wort) may lead to decreased omeprazole serum levels by increasing omeprazole's rate of metabolism.

Pregnancy and Lactation:

Pregnancy

Results from three prospective epidemiological studies (more than 1000 exposed outcomes) indicate no adverse effects of omeprazole on pregnancy or on the health of the foetus/newborn child. Omeprazole can be used during pregnancy.

Lactation

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

Driving and using machines

Omeprazole is not likely to affect the ability to drive or use machines. Adverse drug reactions such as dizziness and visual disturbances may occur. If affected, patients should not drive or operate machinery.

3. HOW TO USE OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg

Posology:

Adults

Treatment of duodenal ulcers

The recommended dose in patients with an active duodenal ulcer is Omeprazole 20mg once daily. In most patients healing occurs within two weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further two weeks treatment period. In patients with poorly responsive duodenal ulcer Omeprazole 40mg once daily is recommended and healing is usually achieved within four weeks.

Prevention of relapse of duodenal ulcers

For the prevention of relapse of duodenal ulcer in H. pylori negative patients or when H. pylori eradication is not possible the recommended dose is Omeprazole 20mg once daily. In some patients a daily dose of 10mg may be sufficient. In case of therapy failure, the dose can be increased to 40mg.

Treatment of gastric ulcers

The recommended dose is Omeprazole 20mg once daily. In most patients healing occurs within four weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further four weeks treatment period. In patients with poorly responsive gastric ulcer Omeprazole 40mg once daily is recommended and healing is usually achieved within eight weeks.

Prevention of relapse of gastric ulcers

For the prevention of relapse in patients with poorly responsive gastric ulcer the recommended dose is Omeprazole 20mg once daily. If needed the dose can be increased to Omeprazole 40mg once daily.

H. pylori eradication in peptic ulcer disease

For the eradication of H. pylori the selection of antibiotics should consider the individual patient's drug tolerance, and should be undertaken in accordance with national, regional and local resistance patterns and treatment guidelines.

- Omeprazole 20mg + clarithromycin 500mg + amoxicillin 1,000mg, each twice daily for one week, or
- Omeprazole 20mg + clarithromycin 250mg (alternatively 500mg) + metronidazole 400mg (or 500mg or tinidazole 500mg), each twice daily for one week or
- Omeprazole 40mg once daily with amoxicillin 500mg and metronidazole 400mg (or 500mg or tinidazole 500mg), both three times a day for one week.

In each regimen, if the patient is still *H. pylori* positive, therapy may be repeated.

Treatment of NSAID-associated gastric and duodenal ulcers

For the treatment of NSAID-associated gastric and duodenal ulcers, the recommended dose is Omeprazole 20mg once daily. In most patients healing occurs within four weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further four weeks treatment period.

Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk

For the prevention of NSAID-associated gastric ulcers or duodenal ulcers in patients at risk (age > 60, previous history of gastric and duodenal ulcers, previous history of upper GI bleeding) the recommended dose is Omeprazole 20mg once daily.

Treatment of reflux oesophagitis

The recommended dose is Omeprazole 20mg once daily. In most patients healing occurs within four weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further four weeks treatment period.

In patients with severe oesophagitis Omeprazole 40mg once daily is recommended and healing is usually achieved within eight weeks.

Long-term management of patients with healed reflux oesophagitis

For the long-term management of patients with healed reflux oesophagitis the recommended dose is Omeprazole 10mg once daily. If needed, the dose can be increased to Omeprazole 20-40mg once daily.

Treatment of symptomatic gastro-oesophageal reflux disease

The recommended dose is Omeprazole 20mg daily. Patients may respond adequately to 10mg daily, and therefore individual dose adjustment should be considered.

If symptom control has not been achieved after four weeks treatment with Omeprazole 20mg daily, further investigation is recommended.

Treatment of Zollinger-Ellison syndrome

In patients with Zollinger-Ellison syndrome the dose should be individually adjusted and treatment continued as long as clinically indicated. The recommended initial dose is Omeprazole 60mg daily. All patients with severe disease and inadequate response to other therapies have been effectively controlled and more than 90% of the patients maintained on doses of Omeprazole 20-120mg daily. When dose exceed Omeprazole 80mg daily, the dose should be divided and given twice daily.

Paediatric population

Children over 1 year of age and ≥ 10 kg

Treatment of reflux oesophagitis

Symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease

The posology recommendations are as follows:

Age Weight Posology

≥ 1 year of age 10-20kg 10mg once daily. The dose can be increased to 20mg once daily if needed

≥ 2 years of age > 20kg 20mg once daily. The dose can be increased to 40mg once daily if needed

Reflux oesophagitis: The treatment time is 4-8 weeks.

Symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease: The treatment time is 2-4 weeks. If symptom control has not been achieved after 2-4 weeks the patient should be investigated further.

Children and adolescents over 4 years of age

Treatment of duodenal ulcer caused by *H. pylori*

When selecting appropriate combination therapy, consideration should be given to official national, regional and local guidance regarding bacterial resistance, duration of treatment (most commonly 7 days but sometimes up to 14 days), and appropriate use of antibacterial agents.

The treatment should be supervised by a specialist.

The posology recommendations are as follows:

Weight

Posology

15-30kg

Combination with two antibiotics: Omeprazole 10mg, amoxicillin 25mg/kg body weight and clarithromycin 7.5mg/kg body weight are all administered together two times daily for one week.

31-40kg

Combination with two antibiotics: Omeprazole 20mg, amoxicillin 750mg and clarithromycin 7.5mg/kg body weight are all administered two times daily for one week.

>40kg

Combination with two antibiotics: Omeprazole 20mg, amoxicillin 1g and clarithromycin 500mg are all administered two times daily for one week.

Special populations

Renal impairment

Dose adjustment is not needed in patients with impaired renal function.

Hepatic impairment

In patients with impaired hepatic function a daily dose of 10-20mg may be sufficient.

Elderly (> 65 years old)

Dose adjustment is not needed in the elderly.

Method of administration

It is recommended to take Omeprazole capsules in the morning, swallowed whole with half a glass of water. The capsules must not be chewed or crushed.

For patients with swallowing difficulties and for children who can drink or swallow semi-solid food

Patients can open the capsule and swallow the contents with half a glass of water or after mixing the contents in a slightly acidic fluid e.g., fruit juice or applesauce, or in non-carbonated water. Patients should be advised that the dispersion should be taken immediately (or within 30 minutes) and always be stirred just before drinking and rinsed down with half a glass of water.

Alternatively patients can suck the capsule and swallow the pellets with half a glass of water. The enteric coated pellets must not be chewed.

Contraindications

Hypersensitivity to omeprazole, substituted benzimidazoles or to any of the excipients listed in section 6.1.

Omeprazole like other proton pump inhibitors (PPIs) must not be used concomitantly with nelfinavir.

4. POSSIBLE SIDE EFFECTS

The most common side effects (1-10% of patients) are headache, abdominal pain, constipation, diarrhoea, flatulence and nausea/vomiting.

The following adverse drug reactions have been identified or suspected in the clinical trials programme for omeprazole and post-marketing. None was found to be dose-related. Adverse reactions listed below are classified according to frequency and System Organ Class (SOC). Frequency categories are defined according to the following convention: Very common ($\geq 1/10$), Common ($\geq 1/100$ to $< 1/10$), Uncommon ($\geq 1/1,000$ to $< 1/100$), Rare ($\geq 1/10,000$ to $< 1/1,000$), Very rare ($< 1/10,000$), Not known (cannot be estimated from the available data).

SOC/frequency	Adverse reaction
Blood and lymphatic system disorders	
Rare:	Leukopenia, thrombocytopenia
Very rare:	Agranulocytosis, pancytopenia
Immune system disorders	
Rare:	Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock
Metabolism and nutrition disorders	
Rare:	Hyponatraemia
Not Known:	Hypomagnesaemia (see section 4.4)
Psychiatric disorders	
Uncommon:	Insomnia
Rare:	Agitation, confusion, depression
Very rare:	Aggression, hallucinations
Nervous system disorders	
Common:	Headache
Uncommon:	Dizziness, paraesthesia, somnolence
Rare:	Taste disturbance
Eye disorders	
Rare:	Blurred vision
Ear and labyrinth disorders	
Uncommon:	Vertigo
Respiratory, thoracic and mediastinal disorders	
Rare:	Bronchospasm
Gastrointestinal disorders	
Common:	Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, Fundic gland

	polyps (benign)
Rare:	Dry mouth, stomatitis, gastrointestinal candidiasis
Not Known	microscopic colitis
Hepatobiliary disorders	
Uncommon:	Increased liver enzymes
Rare:	Hepatitis with or without jaundice
Very rare:	Hepatic failure, encephalopathy in patients with pre-existing liver disease
Skin and subcutaneous tissue disorders	
Uncommon:	Dermatitis, pruritus, rash, urticaria
Rare:	Alopecia, photosensitivity
Very rare:	Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)
Not known:	Subacute cutaneous lupus erythematosus (see section 4.4)
Musculoskeletal and connective tissue disorders	
Uncommon:	Fracture of the hip, wrist or spine (see section 4.4)
Rare:	Arthralgia, myalgia
Very rare:	Muscular weakness
Renal and urinary disorders	
Rare:	Interstitial nephritis
Reproductive system and breast disorders	
Very rare:	Gynaecomastia
General disorders and administration site conditions	
Uncommon:	Malaise, peripheral oedema
Rare:	Increased sweating

Paediatric population

The safety of omeprazole has been assessed in a total of 310 children aged 0 to 16 years with acid-related disease. There are limited long term safety data from 46 children who received maintenance therapy of omeprazole during a clinical study for severe erosive esophagitis for up to 749 days. The adverse event profile was generally the same as for adults in short- as well as in long-term treatment. There are no long term data regarding the effects of omeprazole treatment on puberty and growth.

Reporting of suspected adverse reactions

Reporting suspected adverse reaction after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

OVERDOSAGE:

There is limited information available on the effects of overdoses of omeprazole in humans. In the literature, doses of up to 560 mg have been described, and occasional reports have been received when single oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose). Nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache have been reported. Also apathy, depression and confusion have been described in single cases.

The symptoms described have been transient, and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.

5. HOW TO STORE OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg

Keep out of the sight and reach of children.

Store below 30°C. Protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg contains:

The active ingredient is Omeprazole USP (As enteric coated granules).

What OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg looks like and contents of the pack:

OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg is Pinc coloured cap and white coloured body of hard gelatin capsule size 2 containing white enteric coated pellets.

OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20mg is packed in Alu-Alu blister pack of 10 x 10 Capsules.

Manufacturer

Ciron Drugs and Pharmaceuticals Pvt. Ltd.

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This leaflet was last approved on FEB 2020.