



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 12 November 2024

EL (24)A/54

DMRC Ref: DMRC-32786665

Dear Healthcare Professional,

Viartis UK Healthcare Ltd

Omeprazole 40 mg Powder for solution for infusion

PL 04569/1022

SNOMED Code: 35775411000001106

Batch Number	Expiry Date	Pack Size	First Distributed
C017	Feb-25	5	19-Nov-23
D006Y	Jun-25	5	01-Mar-24

Active Pharmaceutical Ingredient: Omeprazole

Brief description of the problem

Generics (U.K.) Limited (Marketing Authorisation Holder), a Viartis UK Healthcare Limited company, has informed the MHRA that the Patient Information Leaflet (PIL) packaged in the above specified batches of Omeprazole 40 mg Powder for solution for infusion do not contain the most up to date safety information. The affected sections of the PIL are summarised in Appendix 1 of this notification.

Advice for healthcare professionals

There is no risk to the product quality of the medicine listed in this notification. Viartis UK Healthcare Ltd has confirmed that all future batches of the product will contain the updated PIL.

Healthcare professionals are advised to ensure that patients are aware of the updated safety information before administering the product the affected batches of product. Please provide a copy of the updated PIL and remind the patient to read the entire leaflet before taking the medicine. The electronic versions of the PIL are up to date and can be accessed via the following links:

[Omeprazole 40 mg, powder for solution for infusion. - Patient Information Leaflet \(PIL\)](#)

Hard copies of the updated PIL can also be requested from Viartis UK Healthcare Ltd (see contact details below) so that current stock in the dispensary can be supplemented with the correct PIL.



Medicines & Healthcare products Regulatory Agency

Advice for patients

The medicine itself is not affected and patients do not need to take any action. Patients should continue to receive this medicine from these batches as given to you by your healthcare professional.

Patients should be aware that the Patient Information Leaflet included in the packs of the above specified batches of medicines does not contain the most up to date safety information. The affected information is summarised in Appendix 1 of this notification. Your healthcare professional will ensure that you have access to the most up-to-date information associated with the medicines you are receiving.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA [Yellow Card scheme](#).

Further Information

For medical information and stock control queries please contact:

Viatrix UK Healthcare Limited Medical Information at +44 (0)1707 853 000 (select option 1) or info.uk@viatrix.com. Customer Services can be reached at +44 (0)1707 853 000 (select option 2).

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk



Appendix 1

Affected texts in the older PIL text and updated texts in the current-approved PIL (in bold)

Section	Affected texts in older PIL	Updated texts in current approved PIL
<p>Section 2. What you need to know before Omeprazole is given to you</p> <p><u>You must not be given Omeprazole:</u></p>	<ul style="list-style-type: none">- if you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).- if you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).- if you are taking a medicine containing nelfinavir (used for HIV infection).	<ul style="list-style-type: none">- if you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).- if you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).- if you are taking a medicine containing nelfinavir (used for HIV infection).- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Omeprazole.
<p><u>Warnings and precautions</u></p>	<p>Talk to your doctor, pharmacist or nurse before you are given Omeprazole, if:</p> <ul style="list-style-type: none">- You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid .- You are due to have a specific blood test (Chromogranin A).	<p>Do not use Omeprazole if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given this medicine.</p> <p>Talk to your doctor, nurse or pharmacist before you are given Omeprazole.</p> <p>Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with Omeprazole treatment. Stop using Omeprazole and seek medical attention immediately if you notice any of the symptoms related to these</p>



	<p>Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given Omeprazole or after you are given it, talk to your doctor straight away:</p> <ul style="list-style-type: none">- You lose a lot of weight for no reason and have problems swallowing- You get stomach pain or indigestion- You begin to vomit food or blood- You pass black stools (blood-stained faeces)- You experience severe or persistent diarrhoea, as Omeprazole has been associated with a small increase in infectious diarrhoea- You have severe liver problems.	<p>serious skin reactions described in section 4.</p> <p>Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given Omeprazole or after you are given it, talk to your doctor straight away:</p> <ul style="list-style-type: none">- You lose a lot of weight for no reason and have problems swallowing- You get stomach pain or indigestion- You begin to vomit food or blood- You pass black stools (blood-stained faeces)- You experience severe or persistent diarrhoea, as Omeprazole has been associated with a small increase in infectious diarrhoea- You have severe liver problems- You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid- You are due to have a specific blood test (Chromogranin A) <p>When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.</p>
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	<p>Breast-feeding Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Omeprazole if you are breastfeeding.</p>	<p>medicine. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Omeprazole if you are breastfeeding.</p>
<p>Section 3. How Omeprazole is given to you:</p> <p><u>If you are given more Omeprazole than you should</u></p>	<p>If you think you have been given too much Omeprazole, talk to your doctor straight away.</p>	<p>If you think you have been given too much Omeprazole, talk to your doctor straight away.</p> <p>If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.</p>
<p>Section 4 Possible side effects</p>	<p>If you notice any of the following rare but serious side effects, stop using Omeprazole and contact a doctor immediately:</p> <ul style="list-style-type: none">- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction)- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.	<p>If you notice any of the following rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) but serious side effects, stop using Omeprazole and contact a doctor immediately:</p> <ul style="list-style-type: none">- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction). The frequency of this side effect is rare.- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'. The frequency of this side effect is very rare.- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug



<p><u>Other side effects include:</u></p>	<p>Other side effects include: Common side effects (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none">- Headache- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence), benign polyps in the stomach- Feeling sick (nausea) or being sick (vomiting). <p>Rare side effects (may affect up to 1 in 1,000 people):</p> <ul style="list-style-type: none">- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps	<p>hypersensitivity syndrome). The frequency of this side effect is rare.</p> <ul style="list-style-type: none">- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). The frequency of this side effect is rare.- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. The frequency of this side effect is rare. <p>Other side effects include: Common side effects (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none">- Headache- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence), benign polyps in the stomach- Feeling sick (nausea) or being sick (vomiting).- Benign polyps in the stomach. <p>Rare side effects (may affect up to 1 in 1,000 people):</p> <ul style="list-style-type: none">- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps
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	<ul style="list-style-type: none">- Feeling agitated, confused or depressed- Taste changes- Eyesight problems such as blurred vision- Suddenly feeling wheezy or short of breath (bronchospasm)- Dry mouth- An inflammation of the inside of the mouth- An infection called “thrush” which can affect the gut and is caused by a fungus- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness- Hair loss (alopecia)- Skin rash on exposure to sunshine- Joint pains (arthralgia) or muscle pains (myalgia)- Severe kidney problems (interstitial nephritis)- Increased sweating- Inflammation in the gut (leading to diarrhoea). <p>Not known side effects (frequency cannot be estimated from the available data):</p> <ul style="list-style-type: none">- Rash, possibly with pain in the joints- If you are on Omeprazole 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	<ul style="list-style-type: none">- Feeling agitated, confused or depressed- Taste changes- Eyesight problems such as blurred vision- Suddenly feeling wheezy or short of breath (bronchospasm)- Dry mouth- An inflammation of the inside of the mouth- An infection called “thrush” which can affect the gut and is caused by a fungus- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness- Hair loss (alopecia)- Skin rash on exposure to sunshine- Joint pains (arthralgia) or muscle pains (myalgia)- Severe kidney problems (interstitial nephritis)- Increased sweating <p>Not known side effects (frequency cannot be estimated from the available data):</p> <ul style="list-style-type: none">- Rash, possibly with pain in the joints- Inflammation in the gut (leading to diarrhoea).- If you are on Omeprazole 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
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	<p>reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.</p>	<p>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.</p>
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